

Exhibit K

Peggy Pence, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

MDL NO. 2327
HON. JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATED TO THE
FOLLOWING CASES IN WAVE 1 OF
MDL 200:

Donna Amsden v. Ethicon, Inc.
Civil Action No. 2:12-cv-00960

Marie Banks v. Ethicon, Inc.
Civil Action No. 2:12-cv-01318

Harriet Beach v. Ethicon, Inc.
Civil Action No. 2:12-cv-00476

Sharon Boggs, et al. v.
Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00368

DEPOSITION OF
PEGGY PENCE, PH.D.
MARCH 9, 2016

Karen Bollinger v. Ethicon,
Inc.
Civil Action No. 2:12-cv-01215

Robin Bridges v. Ethicon,
Inc., et al.
Civil Action No. 2:12-cv-00651

Denise Burkhart v. Ethicon,
Inc., et al.
Civil Action No. 2:12-cv-01023

Myra Byrd, et al., v. Ethicon,
Inc., et al.
Civil Action No. 2:12-cv-00748

Sharon Carpenter, et al. v.
Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00554

Peggy Pence, Ph.D.

Page 2	Page 4
<p>1 Carey Beth Cole, et al. v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00483 3 Angela Coleman, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-01267 5 Fran Denise Collins v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00931 7 Mary F. Cone v. Ethicon, Inc. Civil Action No. 2:12-cv-00261 8 9 Patricia Conti v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00516 10 11 Amanda Deleon et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00358 12 13 Dina Destefano-Raston, et al. v. Ethicon, Inc. Civil Action No. 2:12-cv-01299 14 15 Karyn E. Drake, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00747 16 17 Paula Fisk v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00848 18 19 Karen Forester, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00486 20 21 Sherry Fox, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00878 22 23 Pamela Free v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00423 24 25 Shirley Freeman, et al. v. Ethicon, Inc., et al.</p>	<p>1 Wilma Johnson v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00809 3 Holly Jones, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00443 5 Barbara Kaiser v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00887 7 Margaret Kirkpatrick v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00746 9 Paula Kriz, et al. v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00938 11 Alfreda Lee, et al. v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01013 13 JoAnn Lehman v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00517 15 Heather Long v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01275 17 Donna Loustaunau, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00666 19 Deborah Lozano, et al. v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-00347 21 Dee McBrayer, et al. v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00779 23 Charlene Miracle v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00510 25</p>
Page 3	Page 5
<p>1 Betty Funderburke v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00957 3 Teresa Georgilakis, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00829 5 Rose Gomez, et al. v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00344 7 Louise Grabowski v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00683 9 Pamela Gray-Wheeler v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00455 11 Susan Guinn v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01121 13 Dawna Hankins v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00369 15 Donna Hankins, et al. v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01011 17 Mary Hendrix, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00595 19 Rocio Herrera-Nevarez v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-01294 21 Barbara Hill, et al. v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00806 23 Nancy Hooper, et al. v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00493 25</p>	<p>1 Cynthia Nix v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-01278 3 Mary Jane Olson, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00470 5 Noemi Padilla v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00567 7 Miranda Patterson v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00481 9 Jennifer Reyes, et al. v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-05664 11 Penny Rhynehart v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01119 13 Ana Ruebel v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00663 15 Patricia Ruiz v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01021 17 Stacy Shultis, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00654 19 Jennifer Sikes, et al. v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-00501 21 Carrie Smith v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00258 23 Janet Smith, et al. v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00861 25</p>

Peggy Pence, Ph.D.

Page 6	Page 8
<p>1 Cherise Springer, et al. v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00997 3 Isabel Swint, et al v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00786 5 Krystal Teasley v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00500 7 Susan Thaman v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00279 9 Kimberly Thomas v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00499 11 Mary Thurston v. Ethicon, Inc. Civil Action No. 2:12-cv-00505 12 13 Patricia Tyler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00469 14 15 Cathy Warlick v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-0276 16 17 Nancy Williams v. Ethicon, Inc. Civil Action No. 2:12-cv-00511 18 19 Christine Wiltgen, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01216 20 21 Sandra Wolfe v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-0335 22 23 Rebecca Pratt v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01273 24 25</p>	<p>1 INDEX 2 WITNESS: PEGGY PENCE, PH.D. 3 EXAMINATION PAGE 4 Ms. Sutherland 10 5 Mr. Kuntz 96 6 7 8 9 EXHIBITS 10 NUMBER PAGE 11 Exhibit 1 Notice to Take Deposition of Peggy 14 Pence 12 13 Exhibit 2 Rule 26 Expert Report of Dr. Peggy 20 Pence 14 Exhibit 3 Supplemental Expert Report of Peggy 21 Pence, Ph.D., Regarding Ethicon 15 Women's Health and Urology 16 Exhibit 4 Supplemental Report of Peggy Pence, 51 Ph.D., Regarding Tension Free 17 Vaginal Tape 18 Exhibit 5 Binder titled "Proxima Systems" 16 with February 1, 2016, expert 19 report and March 2016 supplemental report of Peggy Pence 20 21 Exhibit 6 Binder of supporting documentation 17 for expert report and supplemental report of Peggy Pence 22 23 Exhibit 7 Binder containing FDA documents 18 24 25 Exhibit 8 Binder containing white labeling 18 GHTF final guidance documents</p>
Page 7	Page 9
<p>1 2 Deposition of PEGGY PENCE, PH.D., taken 3 on behalf of the Defendants, before Kristi Johnson, 4 CSR No. 12585, commencing on Wednesday, March 9, 2016, 5 at 9:12 a.m., at 100 Bayview Circle, Suite 5600, Newport 6 Beach, California, pursuant to Notice of Taking Deposition. 7 8 9 APPEARANCES OF COUNSEL: 10 11 For the Plaintiff: 12 WAGSTAFF & CARTMELL BY: JEFFREY KUNTZ, ESQ. 13 4740 Grand Avenue Suite 300 14 Kansas City, Missouri 64112 816.701.1124 15 JKuntz@wcllp.com 16 For the Defendant: 17 BUTLER SNOW LLP BY: KARI SUTHERLAND, ESQ. 18 1020 Highland Colony Parkway Suite 1400 19 Ridgeland, Mississippi 39158-6010 601.985.4523 20 Kari.Sutherland@butlersnow.com 21 22 23 24 25</p>	<p>1 INDEX (Continued) 2 3 EXHIBITS 4 NUMBER PAGE 5 Exhibit 9 Memorandum of Opinion and Order of 27 Judge Goodwin in Mathison vs. 6 Boston Scientific Corporation 7 Exhibit 10 Global Harmonization Task Force, 70 Essential Principles of Safety and 8 Performance of Medical Devices 9 Exhibit 11 Global Harmonization Task Force, 72 Clinical Evaluation 10 11 Exhibit 12 Global Harmonization Task Force, 86 Label and Instructions for Use for 12 Medical Devices 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

3 (Pages 6 to 9)

Peggy Pence, Ph.D.

Page 10	Page 12
<p>1 NEWPORT BEACH, CALIFORNIA; WEDNESDAY, MARCH 9, 2015</p> <p>2 9:12 A.M.</p> <p>3 ---</p> <p>4 PEGGY PENCE, PH.D.,</p> <p>5 called as a witness, having been first duly sworn, was</p> <p>6 examined and testified as follows:</p> <p>7 ---</p> <p>8 EXAMINATION</p> <p>9 BY MS. SUTHERLAND:</p> <p>10 Q. Good morning.</p> <p>11 A. Good morning.</p> <p>12 Q. Would you please tell me your full name?</p> <p>13 A. Peggy Jo Clark Pence.</p> <p>14 Q. Dr. Pence, what is your address?</p> <p>15 A. 1533 Miramar Drive, Newport Beach, California</p> <p>16 92661.</p> <p>17 Q. Is that your business address?</p> <p>18 A. It is my home address as well as I have an</p> <p>19 office there as well, and then I have a satellite office</p> <p>20 in Newbury Park.</p> <p>21 Q. You used to live where before?</p> <p>22 A. Newbury Park.</p> <p>23 Q. So you still have that. Is that where your</p> <p>24 employees are?</p> <p>25 A. We all work remotely. It's an address for a</p>	<p>1 will be my sixth year to teach this specific course.</p> <p>2 Q. Did you teach on GHTF last year?</p> <p>3 A. Yes.</p> <p>4 Q. The year before that?</p> <p>5 A. I don't recall without checking back on my</p> <p>6 notes and PowerPoint slides because I update them every</p> <p>7 year. Let me say I suspect, to the best of my</p> <p>8 recollection, that I did because I have always also</p> <p>9 taught an international conference on harmonization,</p> <p>10 which is relevant to drugs, and the GHTF is analogous to</p> <p>11 the international conference on harmonization but for</p> <p>12 medical devices, GHTF for medical devices. And I teach</p> <p>13 about both medical devices and drugs. So I suspect I</p> <p>14 have been doing it for several years. I just would have</p> <p>15 to -- to the extent to which I have been talking about</p> <p>16 it, because there's a lot to cover, and essentially, I</p> <p>17 have 12 weeks to cover a tremendous amount of material</p> <p>18 So the extent to which I addressed it, I don't recall</p> <p>19 specifically as I sit here today without checking back</p> <p>20 thinking back to two years ago.</p> <p>21 Q. I'm sorry, the last part of that was?</p> <p>22 A. You had asked me about two years ago did I</p> <p>23 teach it.</p> <p>24 Q. So the answer was you think you have taught it</p> <p>25 longer than two years ago?</p>
Page 11	Page 13
<p>1 satellite office, but we're all working remotely from our</p> <p>2 homes at this point in time.</p> <p>3 Q. Are you still teaching?</p> <p>4 A. Yes.</p> <p>5 Q. Are you currently teaching or about to start?</p> <p>6 A. My class starts April 5th.</p> <p>7 Q. How long will that be?</p> <p>8 A. It goes through the end of June.</p> <p>9 Q. And remind me what you teach?</p> <p>10 A. Clinical trials and quality assurance. Biology</p> <p>11 516, if I recall correctly, is the number. It's a</p> <p>12 graduate-level course for students that are working on</p> <p>13 their master's in biotechnology at California State</p> <p>14 University, and I teach that course at the Channel</p> <p>15 Islands campus.</p> <p>16 Q. As part of the class you teach, I would assume</p> <p>17 you include teaching on FDA regulations?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Do you also include teaching on Global</p> <p>20 Harmonization Task Force guidances?</p> <p>21 A. Yes, I do.</p> <p>22 Q. How long have you been including the GHTF</p> <p>23 guidances as part of your course material?</p> <p>24 A. Without checking back on my PowerPoint slides,</p> <p>25 I can't tell you exactly when I began doing that. This</p>	<p>1 A. This is my sixth year to teach this particular</p> <p>2 class.</p> <p>3 Q. You think you have taught on GHTF longer than</p> <p>4 the last two years, but you would have to check to be</p> <p>5 sure. Would that be fair?</p> <p>6 A. Yes.</p> <p>7 Q. On your GHTF course material, do you use</p> <p>8 specific guidances?</p> <p>9 A. I give them guidances to review as part of -- I</p> <p>10 present certain information in class, and then for</p> <p>11 various reading material to support what I present to</p> <p>12 them in class, I give them various guidances, whether</p> <p>13 it's drug or medical device related, and that would</p> <p>14 include GHTF guidances. And, for example, they always</p> <p>15 have an individual -- at least one, if not more,</p> <p>16 individual project assignment that they have to research</p> <p>17 and present prior to the end of class, and some of those</p> <p>18 are drug related, some of those are medical device</p> <p>19 related. I give them as resource materials the guidances</p> <p>20 and instruct them on their own as well to review those</p> <p>21 guidances and incorporate those into their thinking and</p> <p>22 their conclusions, their analyses of the problems that I</p> <p>23 give them to report on.</p> <p>24 Q. Now, do you typically, if you can recall,</p> <p>25 utilize specific GHTF guidances? In other words, could</p>

4 (Pages 10 to 13)

Peggy Pence, Ph.D.

<p style="text-align: right;">Page 14</p> <p>1 you name them for me, the ones you use in class?</p> <p>2 A. I'd have to check back to tell you specifically</p> <p>3 the ones that I use in class, but more than likely, they</p> <p>4 would be the essential principles of safety and</p> <p>5 performance. They would have to do with the clinical</p> <p>6 evaluation, labeling guidances, conformity assessment</p> <p>7 guidances. Also, I usually have a guest speaking that</p> <p>8 comes in and talks about quality management systems, so</p> <p>9 it would include the guidances on quality management</p> <p>10 systems that they would have as well, clinical</p> <p>11 investigations.</p> <p>12 Q. Do you have a syllabus that you have already</p> <p>13 put together for the upcoming class that you're going to</p> <p>14 teach in April?</p> <p>15 A. Not yet. Been too busy.</p> <p>16 Q. Do you need to get working on that?</p> <p>17 A. Yes. I'm waiting on the contract, and then it</p> <p>18 will happen in the next couple of weeks.</p> <p>19 MS. SUTHERLAND: I'm going to hand you what I</p> <p>20 marked as Depo Number 1 and that's your notice.</p> <p>21 (Defendant's Exhibit 1 was marked for</p> <p>22 identification by the court reporter.)</p> <p>23 BY MS. SUTHERLAND:</p> <p>24 Q. Did you bring some documents with you today?</p> <p>25 A. I did.</p>	<p style="text-align: right;">Page 16</p> <p>1 and have them printed, but it's probably --</p> <p>2 MR. KUNTZ: Whatever you want to do. I think</p> <p>3 the last depo we turned them around pretty quick.</p> <p>4 THE WITNESS: It took them a while to get them</p> <p>5 back to me. I think there was confusion about my</p> <p>6 address. If we can just get them back quickly.</p> <p>7 BY MS. SUTHERLAND:</p> <p>8 Q. While we're here, give me again the street</p> <p>9 address where you want them shipped back?</p> <p>10 A. 1533 Miramar Drive, Newport Beach, California</p> <p>11 92661.</p> <p>12 Q. Would you mind if I put stickers on them, or</p> <p>13 would you like me to tape them, for marking the binders</p> <p>14 as exhibits?</p> <p>15 A. Whatever you want to do.</p> <p>16 MS. SUTHERLAND: I'll stick a sticker on the</p> <p>17 outside, and I'm sure you can scrape it off later.</p> <p>18 I'll mark as Exhibit Number 5 your white binder</p> <p>19 called "Prosima Systems" that is listing your February</p> <p>20 expert report and your March supplemental report, and it</p> <p>21 appears there are three tabs in it and a number of</p> <p>22 colored tabs, five tabs, and supplements.</p> <p>23 (Defendant's Exhibit 5 was marked for</p> <p>24 identification by the court reporter.)</p> <p>25 THE WITNESS: That's the supplement and the</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Can I take a peek at what you brought? Just</p> <p>2 this binder?</p> <p>3 A. No. I have others, too, in case you need them.</p> <p>4 You were asking about GHTF documents. Those</p> <p>5 are ones that have been referenced in my report. I also</p> <p>6 brought FDA proposed orders and the reclassification of</p> <p>7 transvaginal mesh for pelvic organ prolapse repair. This</p> <p>8 is the document, the compilation of the documents that</p> <p>9 are footnoted in my Prosima report.</p> <p>10 Q. Ethicon documents?</p> <p>11 A. Ethicon or other documents that are referenced,</p> <p>12 publications that are referenced in footnotes in the body</p> <p>13 of my main report.</p> <p>14 Q. Now, if I want to get copies of your binders,</p> <p>15 do you remember how we have done that before?</p> <p>16 A. We have done it two ways. Last time they were</p> <p>17 taken and returned to me, but it took a while to get them</p> <p>18 back, so I'm not sure why it took so long. I will need</p> <p>19 them for reference. If they were to be taken, could they</p> <p>20 be returned quickly? That's how we did it the last time.</p> <p>21 Q. If we could -- we'll work with Golkow to make</p> <p>22 sure we have a quick turnaround. Would that be okay with</p> <p>23 you if Kristi took them and then we made an effort to be</p> <p>24 sure we got them back to you?</p> <p>25 A. Yes. We can either do that or I can take them</p>	<p style="text-align: right;">Page 17</p> <p>1 exhibits to the supplement.</p> <p>2 BY MS. SUTHERLAND:</p> <p>3 Q. That will be Number 5, and I will hand that</p> <p>4 back to you.</p> <p>5 Number 6 I will mark -- I knew this looked</p> <p>6 familiar with Cavness marked out and MDL marked on there</p> <p>7 A. My staff knows that Cavness was Prosima.</p> <p>8 Everything that's Prosima, they write Cavness on it.</p> <p>9 MS. SUTHERLAND: So I will mark as Exhibit</p> <p>10 Number 6 your orange binder that has tabs in yellow with</p> <p>11 numbers delineated on the side which would reflect</p> <p>12 footnote numbers?</p> <p>13 THE WITNESS: Yes.</p> <p>14 MS. SUTHERLAND: And if we could, when we get</p> <p>15 those copies made, we'll have the tabs the same that</p> <p>16 delineate the numbers.</p> <p>17 (Defendant's Exhibit 6 was marked for</p> <p>18 identification by the court reporter.)</p> <p>19 BY MS. SUTHERLAND:</p> <p>20 Q. There are orange tabs. Those just separate the</p> <p>21 actual documents?</p> <p>22 A. The pages of the report. The pages of the</p> <p>23 report -- the way Christine put that together was the</p> <p>24 pages of the report, and then behind the pages of the</p> <p>25 report is the documents that are referenced in the</p>

5 (Pages 14 to 17)

Peggy Pence, Ph.D.

<p style="text-align: right;">Page 18</p> <p>1 footnotes for that page.</p> <p>2 Q. Very coordinated. I see what you're saying.</p> <p>3 I'll hand that back to you.</p> <p>4 The next binder that I will mark as Number 7,</p> <p>5 which is just a blue binder that's not labeled and has an</p> <p>6 article in the front flap as well as articles in the</p> <p>7 binder.</p> <p>8 (Defendant's Exhibit 7 was marked for</p> <p>9 identification by the court reporter.)</p> <p>10 BY MS. SUTHERLAND:</p> <p>11 Q. This just looks to be primarily FDA documents?</p> <p>12 A. Yes.</p> <p>13 MS. SUTHERLAND: Then Exhibit 8 is a blue</p> <p>14 binder with white labeling GHTF final guidance documents</p> <p>15 (Defendant's Exhibit 8 was marked for</p> <p>16 identification by the court reporter.)</p> <p>17 BY MS. SUTHERLAND:</p> <p>18 Q. And am I to understand these are the GHTF</p> <p>19 guidance documents in your Prosima report?</p> <p>20 A. Yes, there are initial ones in there as well</p> <p>21 that are not necessarily footnoted in my report.</p> <p>22 Q. Do you know which ones that are additional that</p> <p>23 are not in your report?</p> <p>24 A. I could go through and probably tell you.</p> <p>25 Q. If you can do that quickly, I'd appreciate it</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. What footnote is that?</p> <p>2 A. That is in Exhibit 1. It is Footnote 41 on</p> <p>3 page 8. Let me see if there are any others. On page 11</p> <p>4 of my Exhibit 1, I did not include copies in the binder</p> <p>5 of the GHTF roles and responsibilities, guiding</p> <p>6 principles, and operating procedures. I did not include</p> <p>7 copies of those guidances.</p> <p>8 Q. My original question was were there guidances</p> <p>9 in the binder that you saw that were not listed in your</p> <p>10 report?</p> <p>11 A. Yes.</p> <p>12 Q. Just remind me again, what were those?</p> <p>13 A. The clinical evidence I don't believe is</p> <p>14 referenced and the "Review of Current Requirements on</p> <p>15 Postmarket Surveillance," from a quick review, doesn't</p> <p>16 appear to be included.</p> <p>17 MS. SUTHERLAND: I'm going to hand you what I</p> <p>18 have marked as deposition Exhibit Number 2.</p> <p>19 (Defendant's Exhibit 2 was marked for</p> <p>20 identification by the court reporter.)</p> <p>21 BY MS. SUTHERLAND:</p> <p>22 Q. If you would, identify that for me.</p> <p>23 A. This appears to be my expert report of</p> <p>24 February 1st, 2016, on Prosima.</p> <p>25 Q. That has five exhibits to it?</p>
<p style="text-align: right;">Page 19</p> <p>1 just so I know.</p> <p>2 A. Sure. To the best of my recollection as I sit</p> <p>3 here today.</p> <p>4 Q. I understand. I understand.</p> <p>5 A. The clinical evidence, I would have to double</p> <p>6 check, but the "Postmarket Clinical Follow-Up Studies," I</p> <p>7 would need to check on that. I believe the "Review of</p> <p>8 Current Requirements on Postmarket Surveillance."</p> <p>9 Q. You are listing for me the ones that are not</p> <p>10 listed in your report; is that right?</p> <p>11 A. To the best of my recollection without cross</p> <p>12 referencing my report. I can go through them</p> <p>13 individually and check them pretty quickly.</p> <p>14 Q. I'm running through your footnotes as well just</p> <p>15 to double check the ones you have called out.</p> <p>16 A. They would be predominantly referenced in the</p> <p>17 Exhibit 1. They might be in other places as well, but</p> <p>18 specifically, in Exhibit 1.</p> <p>19 I do note that it looks like I did not include</p> <p>20 in here the "Implementation of Risk Management</p> <p>21 Principles." It doesn't look like I brought a copy of</p> <p>22 that one in the binder.</p> <p>23 I'm sorry, I do have "Postmarket Clinical</p> <p>24 Follow-Up Studies." It is referenced in my Exhibit 1 to</p> <p>25 my supplemental report.</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yes. Shall I check to make sure they are all</p> <p>2 here?</p> <p>3 Q. I think they are. It never hurts to check. I</p> <p>4 think they're separately stapled so you can tell easily.</p> <p>5 A. Yes, there are five exhibits.</p> <p>6 MS. SUTHERLAND: I am going to hand you what I</p> <p>7 have marked as deposition Exhibit Number 3.</p> <p>8 (Defendant's Exhibit 3 was marked for</p> <p>9 identification by the court reporter.)</p> <p>10 BY MS. SUTHERLAND:</p> <p>11 Q. Now, that is what was provided to us in March</p> <p>12 as your supplemental report on Prosima and Prolift; is</p> <p>13 that correct?</p> <p>14 A. That is correct. I'm just checking to make</p> <p>15 sure both exhibits are attached. Yes, they are.</p> <p>16 Q. What was the date of that report, Dr. Pence?</p> <p>17 A. March 3rd, 2016.</p> <p>18 MS. SUTHERLAND: I may ask you some questions</p> <p>19 about that. I'll just put this caveat that I'm not going</p> <p>20 to waive my objections to the late filing of that after</p> <p>21 the plaintiff's expert deadline, be that as it may for</p> <p>22 whatever good that does.</p> <p>23 MR. KUNTZ: I'll have to --</p> <p>24 MS. SUTHERLAND: Say you would object?</p> <p>25 MR. KUNTZ: -- pipe in. I think the rules</p>

6 (Pages 18 to 21)

Peggy Pence, Ph.D.

Page 22	Page 24
<p>1 allows -- frankly, I think it just organized it and 2 tailored it to what we were going to talk about were 3 issues. I don't think there's any new opinions. It is 4 what it is, I agree. 5 BY MS. SUTHERLAND: 6 Q. Is there anything in your supplemental report 7 that you're relying on that was not available to you 8 before February 1, 2016? 9 A. I had not had an opportunity to review 10 Dr. Weisberg's late 2015 testimony with regard to the 11 label changes for Gynemesh PS. 12 Q. Do you know when he was deposed? 13 A. If I recall, it was in November. 14 Q. Twelve and thirteen? 15 A. Yes, of 2015. 16 Q. Do you know if the transcript was available for 17 that prior to February 1, 2016? 18 A. I anticipate it was. 19 Q. When did you get a copy of it? 20 A. I don't recall the exact date. 21 Q. Did you get a copy of it in March? 22 A. No, I did get it prior to that. 23 Q. Did you get a copy of it before your 24 February 2016 Prosima report? 25 A. I don't recall specifically as I sit here</p>	<p>1 Q. I understand that. To get an answer to my 2 question, other than Dr. Weisberg's deposition and the 3 exhibits attached to his deposition, are there other 4 materials that were not available to you prior to 5 February 1, 2016, that you cite in your supplemental 6 report? 7 A. No. 8 Q. Now, in your supplemental report, as I 9 understand it, that applies to, obviously, the Prosima 10 report from February of 2016? 11 A. Yes. 12 Q. And then you reference four Prolift reports; 13 correct? 14 A. Yes. 15 Q. Now, as far as any Ethicon mesh devices to 16 treat prolapse, are those the reports we're talking 17 about? 18 A. Yes. 19 Q. So four for Prolift, one for Prosima, and then 20 the supplement? 21 A. Yes, and two of the Prolift were supplemental 22 reports. 23 Q. Now, when did you draft your supplemental 24 report? 25 A. The March 3rd, 2016, one?</p>
Page 23	Page 25
<p>1 today. 2 MR. KUNTZ: I'll have to make a record because 3 I have to. I don't think that that -- my position is 4 that it's just reliance materials that further support 5 her opinions that she's been given for four or five years 6 in this litigation. It's not a new opinion. In fact, 7 Ethicon changed the IFU to list things she's been saying 8 for three or four years that should have been in the IFU. 9 I don't think it's a new opinion. I think it's 10 supplemental materials that support her opinion, and the 11 rules allow you to file supplemental reliance list 12 30 days before trial. 13 BY MS. SUTHERLAND: 14 Q. Other than Dr. Weisberg's deposition 15 transcript, were there any other materials that weren't 16 available to you before February 1, 2016, in your 17 supplemental report? 18 A. Of course, along with his -- Dr. Weisberg that 19 is -- deposition, the exhibits that were attached to 20 that, of course, but as I stated in my supplemental 21 report, there are no new opinions. I didn't change any 22 opinions. I just provided supplemental to my prior 23 reports, I should say, information that I thought was 24 additionally supportive to my opinions, my prior 25 opinions.</p>	<p>1 Q. Yes, ma'am. 2 A. It would have been late February to early 3 March. 4 Q. Why did you draft it? 5 A. Because I felt after when I reviewed -- when I 6 had an opportunity to review Dr. Weisberg's deposition 7 and the attachment, the exhibits, I mean to say, to that, 8 I recognized that it was additionally supportive of my 9 opinions because the modifications, the revisions to the 10 labeling as regards to risk information, included 11 information that, from my original reports dating back to 12 2012 for my first Prolift report, in fact, contained 13 information that ultimately Ethicon added after they 14 received notification from Health Canada that Health 15 Canada was requesting updates to the labeling. And I 16 thought that was substantiation of my opinions, and it 17 was important to document that. In the course of doing 18 that, I also decided to add some additional information 19 supportive of my opinions about failure to test from 20 other authoritative bodies. 21 Q. Why did you feel like you needed to add other 22 information from other authoritative bodies in your 23 supplemental report? 24 A. I thought it was important to -- I have added 25 it in some other reports that I have done that I hadn't</p>

7 (Pages 22 to 25)

Peggy Pence, Ph.D.

Page 26	Page 28
<p>1 added initially, if I recall correctly as I sit here</p> <p>2 today, in my first Prolift report. And I thought it</p> <p>3 would be helpful and that I would add it as a result of</p> <p>4 that since I was updating the report, and then, of</p> <p>5 course, the GHTF information.</p> <p>6 Q. Is the GHTF information material that was not</p> <p>7 included in your Prolift 2012 report?</p> <p>8 A. That's correct.</p> <p>9 Q. Was the GHTF information included in your -- I</p> <p>10 think it's 2014 Prolift report?</p> <p>11 A. No.</p> <p>12 Q. So the only GHTF information that you have</p> <p>13 supplied now for Prolift is your March 2016 supplemental</p> <p>14 report; is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Did you review any ruling by Judge Goodwin</p> <p>17 addressing the scope of your opinions before you drafted</p> <p>18 your supplemental report?</p> <p>19 MR. KUNTZ: Objection. Vague as to time. What</p> <p>20 opinion?</p> <p>21 BY MS. SUTHERLAND:</p> <p>22 Q. Do you understand my question?</p> <p>23 A. Yes, but if you'll repeat it, please.</p> <p>24 Q. Absolutely. Let me ask it this way: Have you</p> <p>25 ever reviewed any opinion from Judge Goodwin addressing</p>	<p>1 A. You'll note that when I wrote my Prosima</p> <p>2 report, which is dated February 1st, that it has an</p> <p>3 exhibit, the GHTF information, and that is not the first</p> <p>4 report for mesh products where I included GHTF. Back, if</p> <p>5 I'm recalling correctly, in 2014, I wrote a Boston</p> <p>6 Scientific report in which I included GHTF information,</p> <p>7 and so when I wrote the Prosima report, I included the</p> <p>8 GHTF information understanding instead of FDA regulations</p> <p>9 based on my understanding of the concerns about FDA</p> <p>10 sometimes being allowed, sometimes not being allowed, and</p> <p>11 that there are other standards on which to rely. So when</p> <p>12 I was doing the supplement, I realized that I had never</p> <p>13 done that for Prolift. Prolift only has FDA information</p> <p>14 and that it was appropriate and relevant to also include</p> <p>15 the GHTF information for Prolift as well as Prosima.</p> <p>16 Q. Would it be fair to say that you added in the</p> <p>17 GHTF information in your Prosima February 2016 report in</p> <p>18 part because of Judge Goodwin's order excluding opinions</p> <p>19 where you just rely on FDA regulations?</p> <p>20 A. That isn't recent. Although this Exhibit 9 is</p> <p>21 dated May 2015, as I mentioned, I had previously added</p> <p>22 GHTF into a prior report understanding, back a couple</p> <p>23 years or more ago, that at least for the MDL litigation,</p> <p>24 that the FDA was not to be a part of that litigation, and</p> <p>25 there are other standards that the industry relies on</p>
Page 27	Page 29
<p>1 the scope of your opinions that he would allow at trial?</p> <p>2 A. Yes, some time ago I did.</p> <p>3 Q. Did you review an opinion from May of 2015 in a</p> <p>4 Boston Scientific order addressing the scope of your</p> <p>5 opinions?</p> <p>6 A. I don't recall the date of the order</p> <p>7 specifically. If you have it, I can take a look at it</p> <p>8 and tell you if that's what I reviewed.</p> <p>9 MS. SUTHERLAND: I'm going to hand you what I</p> <p>10 am marking as number 9.</p> <p>11 (Defendant's Exhibit 9 was marked for</p> <p>12 identification by the court reporter.)</p> <p>13 BY MS. SUTHERLAND:</p> <p>14 Q. Take a look at that and tell me if that's the</p> <p>15 opinion by Judge Goodwin that you may recall reviewing.</p> <p>16 For ease of reference, your part begins around page 9.</p> <p>17 A. I did find it, thank you. I am going through</p> <p>18 it to see if it seems like what I reviewed. This appears</p> <p>19 to be what I reviewed, if not very similar to what I</p> <p>20 reviewed.</p> <p>21 Q. Dr. Pence, after you reviewed deposition</p> <p>22 Exhibit Number 9, or if I understand your testimony</p> <p>23 correctly an opinion similar to it, did you decide to add</p> <p>24 in information about GHTF to your reports about Ethicon</p> <p>25 mesh?</p>	<p>1 that are relevant internationally, and in particular to</p> <p>2 the U.S. and that the U.S. has participated in</p> <p>3 establishing those standards, so that to exclude other</p> <p>4 standards was not presenting a comprehensive approach to</p> <p>5 the available evidence to support my opinions.</p> <p>6 Q. If I'm understanding you correctly, I believe</p> <p>7 you testified that you're not offering any new opinions</p> <p>8 regarding Prolift other than what was set out in your</p> <p>9 2012 and 2014 reports; correct?</p> <p>10 A. That is correct.</p> <p>11 Q. And in those 2012 and 2014 reports, what you</p> <p>12 relied on to support your opinions in part were FDA</p> <p>13 regulations; correct?</p> <p>14 A. Yes, as a regulatory expert working in the</p> <p>15 United States.</p> <p>16 Q. That would seem to make sense, wouldn't it?</p> <p>17 A. Exactly, but there are additional standards,</p> <p>18 and because I am a regulatory expert working in the U.S.,</p> <p>19 I initially included FDA standards. Recognizing that for</p> <p>20 certain courts that that information may not be allowed</p> <p>21 to be presented, I wanted to provide a more comprehensive</p> <p>22 and broader base for my opinions and reflect the</p> <p>23 international standards, which include much of the same</p> <p>24 types of information, but it's an international standard</p> <p>25 that substantiates my opinions.</p>

8 (Pages 26 to 29)

Peggy Pence, Ph.D.

Page 30	Page 32
<p>1 Q. Is it your testimony that the opinions on</p> <p>2 Prolift that you offered in the 2012 and 2014 reports,</p> <p>3 you're not relying on FDA regulations to support those</p> <p>4 opinions?</p> <p>5 A. No, that's misrepresenting what I'm trying to</p> <p>6 say.</p> <p>7 Q. Then let me follow up.</p> <p>8 Is it your testimony then that, in fact, you</p> <p>9 are still relying on FDA regulations to support the</p> <p>10 opinions you set out in your 2012 and 2014 Prolift</p> <p>11 reports?</p> <p>12 A. The best way to answer that is that both FDA</p> <p>13 regulations and the GHTF guidances support my opinions.</p> <p>14 So I'm not saying that my opinions aren't supported by</p> <p>15 FDA regulations. They are, but my opinions are also</p> <p>16 supported by the GHTF guidance documents. The GHTF --</p> <p>17 the purpose of that was to harmonize international</p> <p>18 standards.</p> <p>19 Q. I'll get to that. Let me get back on track. I</p> <p>20 got off my outline.</p> <p>21 Looking back at your supplemental report, there</p> <p>22 are two exhibits to that; correct?</p> <p>23 A. Yes.</p> <p>24 Q. When I say supplemental report, I know you have</p> <p>25 got a TVT supplemental report I haven't marked yet. For</p>	<p>1 different than Exhibit 1 that goes to the supplemental</p> <p>2 report; correct?</p> <p>3 A. It has some additions.</p> <p>4 Q. The supplemental report has some additions?</p> <p>5 A. Yes.</p> <p>6 Q. Within that month time frame, from February to</p> <p>7 March, why did you add in the supplement additions?</p> <p>8 A. I felt they were helpful.</p> <p>9 Q. Can you tell me which ones you added in?</p> <p>10 A. We can do a comparison here. One thing I know</p> <p>11 for sure that I added was further information on the</p> <p>12 process by which the GHTF documents were developed, and</p> <p>13 that is its own section, Section 4, starting on page 11</p> <p>14 of Exhibit 1 to the supplemental report, titled</p> <p>15 "Supplementary Information Regarding GHTF Procedures:</p> <p>16 All Decisions and Actions By Consensus."</p> <p>17 Q. While we're on that, let me interrupt you for</p> <p>18 just a minute.</p> <p>19 The five study groups that you list there on</p> <p>20 page 11, are those the only five study groups that GHTF</p> <p>21 had during the 20-year time frame that it was ongoing?</p> <p>22 A. To my understanding, that's correct, yes.</p> <p>23 Q. Now let me ask you: Do you know the makeup of</p> <p>24 any of the study groups?</p> <p>25 A. Can you clarify what you mean by makeup?</p>
Page 31	Page 33
<p>1 now I'm focusing on the Prosima and Prolift one I marked.</p> <p>2 There are two exhibits to that; correct?</p> <p>3 A. Yes.</p> <p>4 Q. One is an industry standards document that you</p> <p>5 drafted?</p> <p>6 A. Yes.</p> <p>7 Q. Dated March 3rd, 2016?</p> <p>8 A. Yes.</p> <p>9 Q. And then there's a MAUDE report; correct?</p> <p>10 A. Yes.</p> <p>11 Q. M-A-U-D-E, all caps. Tell Kristi what that</p> <p>12 stands for.</p> <p>13 A. Manufacturer and user facility device</p> <p>14 experience database.</p> <p>15 Q. Now, in your Prosima original report, the</p> <p>16 February 2016 report, you also have an exhibit that is</p> <p>17 applicable industry standards; correct?</p> <p>18 A. I'm sorry, can you repeat that?</p> <p>19 Q. No worries.</p> <p>20 In your original Prosima report from</p> <p>21 February 2016, your first exhibit is also applicable</p> <p>22 industry standards?</p> <p>23 A. Yes.</p> <p>24 Q. Now, Exhibit 1, which is applicable industry</p> <p>25 standards for the February Prosima report, is somewhat</p>	<p>1 Q. Sure.</p> <p>2 As I understand it, GHTF included, obviously,</p> <p>3 regulatory agencies?</p> <p>4 A. Right.</p> <p>5 Q. Did it include industry representatives?</p> <p>6 A. Yes.</p> <p>7 Q. Were consumer representatives included?</p> <p>8 A. It was a mix of regulatory and -- it was a</p> <p>9 partnership, if you will, between regulatory and</p> <p>10 industry. For example, AdvaMed represented -- was</p> <p>11 represented in the various GHTF groups.</p> <p>12 Q. Which ones?</p> <p>13 A. I can't tell you specifically as I sit here</p> <p>14 today.</p> <p>15 Q. During the whole time frame or specific times?</p> <p>16 A. I don't have the information available to tell</p> <p>17 you specifically. I do know they participated, other</p> <p>18 industry representative groups as well participated, some</p> <p>19 specific companies. The aim was to have equal</p> <p>20 representation between regulators and industry groups.</p> <p>21 Q. First of all, let me ask you: How do you know</p> <p>22 AdvaMed was in the study groups?</p> <p>23 A. Because I did some of my own independent</p> <p>24 research and was able to confirm, to the best of my</p> <p>25 recollection. For example, AdvaMed was, I believe Boston</p>

9 (Pages 30 to 33)

Peggy Pence, Ph.D.

Page 34	Page 36
<p>1 Scientific was, to the best of my recollection, I believe</p> <p>2 Medtronic was, some of the ones I was able to find, best</p> <p>3 of my recollection, as I sit here today.</p> <p>4 Q. How did you find them?</p> <p>5 A. By Internet searching and trying to find</p> <p>6 information on the identity of who was in particular</p> <p>7 groups.</p> <p>8 Q. Just trolling through the Internet,</p> <p>9 essentially, to find out?</p> <p>10 A. Doing specifically directed searches looking to</p> <p>11 see what I could find to support that information.</p> <p>12 Q. Now, in your searches, was Ethicon ever a</p> <p>13 member of any of the five study groups at GHTF?</p> <p>14 A. I don't recall seeing Ethicon specifically, as</p> <p>15 I sit here today.</p> <p>16 Q. What about J&J?</p> <p>17 A. A lot of that information just isn't available</p> <p>18 online. I can't say if they were or were not, but they</p> <p>19 were certainly represented by AdvaMed.</p> <p>20 Q. Were they a member of AdvaMed at the time</p> <p>21 AdvaMed was a member of GHTF?</p> <p>22 A. I don't have that specific information as I sit</p> <p>23 here today, but certainly, AdvaMed, the working group</p> <p>24 that put together a presentation for the 2011 advisory</p> <p>25 meeting, Ethicon participated in that and that was</p>	<p>1 sit here today.</p> <p>2 Q. The years that AdvaMed, from what you saw,</p> <p>3 worked with GHTF, do you know those years?</p> <p>4 A. I don't recall those specifically as I sit here</p> <p>5 today.</p> <p>6 Q. Now, if I asked you the same questions with</p> <p>7 respect to Johnson & Johnson, do you know whether or not</p> <p>8 Johnson & Johnson was ever a member of GHTF?</p> <p>9 A. I don't know as I sit here today. I don't have</p> <p>10 a list of all of the membership.</p> <p>11 Q. You did say Boston Scientific; right?</p> <p>12 A. Yes.</p> <p>13 Q. Do you know when Boston Scientific was a member</p> <p>14 of GHTF?</p> <p>15 A. I don't recall the date as I sit here today.</p> <p>16 Q. Do you know which study group they might have</p> <p>17 been in?</p> <p>18 A. I don't recall as I sit here today.</p> <p>19 Q. I was curious on that one.</p> <p>20 What about any other pelvic mesh manufacturer?</p> <p>21 A. As I said earlier, the information on specific</p> <p>22 memberships and the different study groups, although I</p> <p>23 did look for it, I was unable to find a great deal of</p> <p>24 information about that, except to know as it's set out</p> <p>25 that in the membership of GHTF, that it is an equal -- it</p>
Page 35	Page 37
<p>1 through AdvaMed.</p> <p>2 Q. That was for FDA, though; right?</p> <p>3 A. Yes.</p> <p>4 Q. But we're talking about GHTF.</p> <p>5 A. Yes, I understand that, but they were certainly</p> <p>6 working through AdvaMed at that time.</p> <p>7 Q. So let me close the loop on that.</p> <p>8 Do you have information showing that in 2011,</p> <p>9 at the same time that Ethicon was in AdvaMed working for</p> <p>10 the FDA group in 2011, that they were also working in one</p> <p>11 of the study groups in GHTF?</p> <p>12 Was that a convoluted question? I can ask that</p> <p>13 better.</p> <p>14 A. Yes.</p> <p>15 Q. Your pretext or your preface is that Ethicon</p> <p>16 was working with AdvaMed in 2011 during the whole time</p> <p>17 frame with the panel meeting and FDA in 2011?</p> <p>18 A. Yes.</p> <p>19 Q. Now, as I understood your testimony, you</p> <p>20 initially said that you knew that Ethicon was in AdvaMed</p> <p>21 and that AdvaMed was working with GHTF?</p> <p>22 A. I knew that they were a member of AdvaMed.</p> <p>23 Based on the information that I have, it appears that</p> <p>24 they're a member of AdvaMed. The years of their</p> <p>25 membership, I don't have that information available as I</p>	<p>1 was, as you know, disbanded and transferred to IMDRF,</p> <p>2 which is all regulators. But during its 20-year history,</p> <p>3 the aim was to be an equal partnership between industry</p> <p>4 and the regulators internationally with the five founding</p> <p>5 members, and then there's some additional groups that</p> <p>6 joined as well in 2006.</p> <p>7 Q. Why did it disband, GHTF, do you know?</p> <p>8 A. I don't have specific reason to offer as to why</p> <p>9 they disbanded. They did transfer their work over to</p> <p>10 IMDRF, and it's made up of voluntary membership of</p> <p>11 regulators, IMDRF.</p> <p>12 Q. Is FDA a member of IMDRF?</p> <p>13 A. Yes. To my understanding, that's correct.</p> <p>14 Q. When did GHTF disband?</p> <p>15 A. 2012.</p> <p>16 Q. Did IMDRF, to your knowledge, ever make some</p> <p>17 sort of statement adopting the GHTF guidances?</p> <p>18 A. Yes. If you go on the IMDRF website, you will</p> <p>19 see that they have GHTF archives, and then they have a</p> <p>20 section where you can have IMDRF documents and GHTF</p> <p>21 documents. And the GHTF documents and all of those that</p> <p>22 are included in the binder that we marked as Exhibit 8</p> <p>23 are considered current based on that website. If you go</p> <p>24 on the IMDRF website, you will see archived documents</p> <p>25 which they will tell you are no longer considered</p>

10 (Pages 34 to 37)

Peggy Pence, Ph.D.

Page 38	Page 40
<p>1 current. They are there for reference. They have a list</p> <p>2 of GHTF documents which are considered current posted on</p> <p>3 their website.</p> <p>4 Q. And the ones that are in your binder and that</p> <p>5 you have relied on in your reports, are they all under</p> <p>6 the current part of the IMDRF website?</p> <p>7 A. Yes. I went through and verified that each one</p> <p>8 is listed still on what's considered current by IMDRF.</p> <p>9 Q. Now let me ask you about Exhibit 2 of your</p> <p>10 supplemental report. That is the MAUDE MDR reports. Let</p> <p>11 me tell you what I think this is and you tell me if I'm</p> <p>12 right.</p> <p>13 As far as I understand it, what you have got</p> <p>14 listed here in the three different charts are reports</p> <p>15 that were reported to FDA that you located on the MAUDE</p> <p>16 database that, in some extent, reference pelvic mesh?</p> <p>17 A. Yes. For these particular products and</p> <p>18 manufacturers, yes.</p> <p>19 Q. Did you do the search?</p> <p>20 A. It was done under my direction by Christine</p> <p>21 Swanson, who is one of my staff.</p> <p>22 Q. What search terms did she use to come up with</p> <p>23 the numbers to populate the different columns?</p> <p>24 A. I would have to -- I would have to present that</p> <p>25 to you as a list. For example --</p>	<p>1 should say.</p> <p>2 Q. I'm trying to follow you there.</p> <p>3 Does she not have a college degree?</p> <p>4 A. I don't believe she does, not a bachelor's.</p> <p>5 Q. She did graduate from high school, though;</p> <p>6 right?</p> <p>7 A. Yes.</p> <p>8 Q. How old is she?</p> <p>9 A. I don't know specifically. We're not allowed</p> <p>10 to ask those questions as an employer.</p> <p>11 Q. She's not a teenager, is she?</p> <p>12 A. No. She has a son that's a teenager.</p> <p>13 Q. Did you look at any of the actual reports</p> <p>14 themselves from the MAUDE database?</p> <p>15 A. Yes.</p> <p>16 Q. Did you look at all of them?</p> <p>17 A. I have not looked at every one, no.</p> <p>18 Q. Can you tell me, on the Ethicon sling column,</p> <p>19 the combined products, there's a total there of 23,083</p> <p>20 MDRs, can you tell me how many reports out of those</p> <p>21 23,000 plus you actually looked at?</p> <p>22 A. I can't give you a specific number, no.</p> <p>23 Q. Did you look at a hundred?</p> <p>24 A. I certainly looked at more than a hundred, yes.</p> <p>25 Q. Of the Ethicon ones?</p>
Page 39	Page 41
<p>1 Q. Did you tell her what to search for?</p> <p>2 A. Yes.</p> <p>3 Q. Tell me what you told her, essentially.</p> <p>4 A. I told her to search from 1999 through the end</p> <p>5 of 2015 for these particular manufacturers and these</p> <p>6 product names. And then for Ethicon, for example, where</p> <p>7 we have combined the sling products, TVT, TVT-O, TVT</p> <p>8 Obturator, TVT Exact, TVT Abbrevio, TVT Secure. She</p> <p>9 applied the manufacturer names, the names of the</p> <p>10 products, and to extract MDR reports that had been</p> <p>11 submitted to the FDA for those particular products for</p> <p>12 those particular manufacturers that are listed here.</p> <p>13 Q. Now, what was the name of the lady that --</p> <p>14 A. Christine Swanson.</p> <p>15 Q. What are her qualifications or background?</p> <p>16 A. She has a great deal of background as an</p> <p>17 analyst, a data analyst.</p> <p>18 Q. Does she have a master's or something?</p> <p>19 A. No.</p> <p>20 Q. Tell me if you know her educational background.</p> <p>21 A. I don't believe she actually has -- to the best</p> <p>22 of my recollection as I sit here today, I don't believe</p> <p>23 she has a bachelor's degree. She has, for example,</p> <p>24 previously worked at Amgen as an analyst and she has</p> <p>25 extensive experience in data analytics, data analysis, I</p>	<p>1 A. Yes.</p> <p>2 Q. Why did you look at them?</p> <p>3 A. Well, I looked at them for a variety of</p> <p>4 reasons. I have reviewed issue reports in the past as</p> <p>5 well, and I reviewed MDR reports to look at the</p> <p>6 information in the MDR reports. First of all, when I</p> <p>7 give my staff direction, I verify what they're doing and</p> <p>8 that it's being done correctly. For example, if you look</p> <p>9 at my Prolift report, which I don't have a copy here --</p> <p>10 Q. It's burned in my brain.</p> <p>11 A. If you look at my Prolift report, if I'm</p> <p>12 recalling correctly as I sit here today, you will see</p> <p>13 there are tabular presentations of particular adverse</p> <p>14 events that are reported in the MDR database. When I</p> <p>15 give my staff direction, in order to present, pull out</p> <p>16 this type of a table, it's a tabulation of numbers of MDR</p> <p>17 reports that come up for specific search terms. But</p> <p>18 within the body of the MDR reports, there's a discussion</p> <p>19 description of the adverse event or events that occurred</p> <p>20 and were reported in the MDR report. For a tabulation</p> <p>21 such as those that were presented in my Prolift report,</p> <p>22 you have to go through and read the MDR report and</p> <p>23 extract the information that shows there's an erosion or</p> <p>24 if there's dyspareunia or whatever the adverse event may</p> <p>25 be.</p>

11 (Pages 38 to 41)

Peggy Pence, Ph.D.

Page 42	Page 44
<p>1 Q. Did you do that for this chart?</p> <p>2 A. This is a tabulation for all MDR reports. It's</p> <p>3 not a tabulation of what the specific adverse events were</p> <p>4 that were reported in those. That information, as you</p> <p>5 know in the Prolift report, there is that type of</p> <p>6 information and we did do that for that.</p> <p>7 Q. Unfortunately, I can't ask you about that</p> <p>8 because you have been deposed in the Prolift report.</p> <p>9 For this report, Exhibit 2 to your supplement,</p> <p>10 would I be correct that you don't have it broken out as</p> <p>11 to what the event is that occurred for, for instance, the</p> <p>12 Ethicon sling products combined?</p> <p>13 A. That's correct. This is a tabulation of the</p> <p>14 total number of MDR reports for these products, these</p> <p>15 manufacturers.</p> <p>16 Q. Do you have that information stored somewhere</p> <p>17 else, like at Symbion?</p> <p>18 A. For some of them we do where we have gone</p> <p>19 through and pulled that information out. It takes,</p> <p>20 obviously, a lot of time to read through each of those</p> <p>21 and to pull the information out and tabulate it, and we</p> <p>22 have done that for a number of these.</p> <p>23 Q. But not for what I'm now looking at as</p> <p>24 Exhibit 2?</p> <p>25 A. For some of those that information is</p>	<p>1 for instance, if someone had both a TVT and a Prolift</p> <p>2 implanted and there was one MDR, do you know where she</p> <p>3 would stick the MDR?</p> <p>4 A. Without checking back with her, I would</p> <p>5 anticipate that it probably would have appeared in both</p> <p>6 columns.</p> <p>7 Q. If I'm looking at the top chart -- and let's</p> <p>8 just stick with the Ethicon sling column for now -- you</p> <p>9 can see it jumps from in 2011, there were 270 reports.</p> <p>10 Do you see where I am?</p> <p>11 A. Yes.</p> <p>12 Q. The next year, 2012, there were over 3,000</p> <p>13 reports?</p> <p>14 A. Correct.</p> <p>15 Q. And then the next year, 2013, there were over</p> <p>16 16,000 reports; right?</p> <p>17 A. Yes.</p> <p>18 Q. First of all, let me ask you, for the year</p> <p>19 where the number was put, is that just the year of the</p> <p>20 report, when the event was reported?</p> <p>21 A. Yes.</p> <p>22 Q. So if the event occurred, say, in 2003, but it</p> <p>23 was reported in 2007, the number goes in 2007?</p> <p>24 A. For this chart, yes.</p> <p>25 Q. For this chart?</p>
Page 43	Page 45
<p>1 available. Not for all of the MDR reports that are in</p> <p>2 this tabulation.</p> <p>3 Q. And the sum that you're talking about that's</p> <p>4 available are set out in your previous Prolift reports?</p> <p>5 A. And other reports.</p> <p>6 Q. And TVT reports?</p> <p>7 A. And also the Boston Scientific, for example.</p> <p>8 Q. Did you make efforts to call out any duplicate</p> <p>9 reports?</p> <p>10 A. We do try to do that, yes.</p> <p>11 Q. Tell me how you try to do that for this</p> <p>12 exhibit, Exhibit 2.</p> <p>13 A. Well, we have done that previously. If it</p> <p>14 appears --</p> <p>15 Q. I want to hear about for this one.</p> <p>16 A. If there's definitely a duplicate. For this, I</p> <p>17 would have to double check exactly how we did it for this</p> <p>18 particular report.</p> <p>19 Q. Do you know, as you sit here today, that</p> <p>20 efforts were, in fact, taken to call out duplicates from</p> <p>21 the numbers that are represented in Exhibit 2?</p> <p>22 A. To the best of my recollection as I sit here</p> <p>23 today, yes. Christine always pays attention to try to</p> <p>24 call out anything that's an obvious duplicate.</p> <p>25 Q. Now, did Christine make efforts to call out,</p>	<p>1 A. Yes.</p> <p>2 Q. Outside a mass litigation like we have here</p> <p>3 with mesh, have you seen numbers jump to the percentage</p> <p>4 that you're seeing here, for instance, from 2012 with</p> <p>5 3,000 reports to 2013 with 16,000 reports? Have you seen</p> <p>6 that outside of litigation?</p> <p>7 A. Well, I have not looked at it for every product</p> <p>8 outside of litigation. For those products that I have</p> <p>9 looked at, I have seen that happen more typically with</p> <p>10 litigation or if there's some kind of a safety alert or</p> <p>11 some type of a notification from the FDA that makes</p> <p>12 people more aware.</p> <p>13 Q. Did you make any notations or record of how</p> <p>14 many of the reports were from litigation?</p> <p>15 A. That information is available. I don't have it</p> <p>16 in this document.</p> <p>17 Q. When you say it's available, it's in the MDR</p> <p>18 report?</p> <p>19 A. Right.</p> <p>20 Q. Do you all have some kind of work product put</p> <p>21 together where you have delineated how many of the 16,000</p> <p>22 are from litigation?</p> <p>23 A. For some of the products we do. For all of the</p> <p>24 totals here, no, but, for example, I don't have it for</p> <p>25 AMS. I do have it for some of these products.</p>

12 (Pages 42 to 45)

Peggy Pence, Ph.D.

Page 46	Page 48
<p>1 Q. Do you have it for Ethicon products?</p> <p>2 A. For some of them, yes.</p> <p>3 Q. Which ones?</p> <p>4 A. I don't remember specifically without checking</p> <p>5 back as I sit here today.</p> <p>6 Q. When you say you have it for some products, are</p> <p>7 you saying for all of the TVT reports from '99 to 2015,</p> <p>8 you may already have that information of how many of</p> <p>9 those reports were from litigation --</p> <p>10 A. Yes.</p> <p>11 Q. -- like for TVT?</p> <p>12 A. Yes. We have done that analysis for a number</p> <p>13 of the different products.</p> <p>14 Q. Up through 2015?</p> <p>15 A. Not completely through 2015 because, if I</p> <p>16 recall correctly as I sit here today, my prior reports</p> <p>17 had not gone through 2015, and for this exhibit, updated</p> <p>18 it through the end of 2015 since we're now into 2016.</p> <p>19 Q. The reason I'm asking is, I think you and I had</p> <p>20 talked before about your previous MAUDE searches, and I</p> <p>21 did not recall that you had pulled out the ones that were</p> <p>22 from litigation. That's what I'm trying to help jog your</p> <p>23 memory if you know which Ethicon devices you have that</p> <p>24 information for. If you don't, you don't.</p> <p>25 A. And maybe calling out, maybe I'm</p>	<p>1 products and that information is certainly available.</p> <p>2 Q. Now, I had asked you before as to, for</p> <p>3 instance, if the patient had been implanted both with an</p> <p>4 Ethicon sling and an Ethicon Prolift, how the numbers</p> <p>5 would splice out, and I think you testified, number one,</p> <p>6 you'd have to check, but number two, you think it might</p> <p>7 appear in both columns?</p> <p>8 A. Yes, I would anticipate it would appear in both</p> <p>9 columns because, if there was an MDR report for TVT and</p> <p>10 you don't include it in TVT, then that's an inappropriate</p> <p>11 representation of the numbers of reports addressing TVT</p> <p>12 saying for Prolift. It would be most appropriate to</p> <p>13 include that in both places. If we were doing a more</p> <p>14 in-depth analysis and we would define -- and we have done</p> <p>15 these types of analysis before -- we would define how</p> <p>16 many of those there were.</p> <p>17 Q. Did you do that same approach, say, if a</p> <p>18 patient was implanted with both an Ethicon product and a</p> <p>19 Boston Scientific product, would the number appear in</p> <p>20 both columns?</p> <p>21 A. Yes.</p> <p>22 Q. Did Christine make any attempt at determining</p> <p>23 whether or not there were some other concomitant causes</p> <p>24 of the list of adverse events?</p> <p>25 A. Not for this tabulation, no.</p>
Page 47	Page 49
<p>1 misunderstanding the question, so let me clarify. We</p> <p>2 didn't call out and not include those because that would</p> <p>3 be inappropriate not to include them.</p> <p>4 Q. It would lower the numbers quite a bit,</p> <p>5 wouldn't it?</p> <p>6 A. Yes. It doesn't mean -- just because it's</p> <p>7 reported in litigation, it doesn't mean they're not real.</p> <p>8 To not include them would not be an appropriate</p> <p>9 representation of the data. And what was done here is</p> <p>10 present an appropriate representation, an accurate</p> <p>11 representation of the numbers in the MDR reports as</p> <p>12 possible. Calling out is not the term that I would use.</p> <p>13 We have done, for some of the products, that analysis</p> <p>14 where we know how many were reported by attorneys based</p> <p>15 on the information that's in the MDR report.</p> <p>16 Q. Is that in previous reports that you have done</p> <p>17 on those devices or is that a separate?</p> <p>18 A. If I'm recalling correctly, as I sit here</p> <p>19 today, some of the reports may include the number that</p> <p>20 were attorney reported, or at least a reference to the</p> <p>21 fact that some may be attorney reported. I don't recall</p> <p>22 specifically without looking back at my reports whether</p> <p>23 or not we gave an actual number, but I know we have done</p> <p>24 that analysis anticipating, for example, that it would be</p> <p>25 of interest to you. We have done that analysis for some</p>	<p>1 Q. You didn't either?</p> <p>2 A. Not for this tabulation. This is specifically</p> <p>3 as it's described a tally of the total numbers of MDR</p> <p>4 reports that were submitted to FDA for the products of</p> <p>5 the manufacturers listed here.</p> <p>6 Q. Now, for the products listed here for the</p> <p>7 years, do you have any sort of denominator number? For</p> <p>8 instance, do you know how many TVT family of slings were</p> <p>9 sold in 2010?</p> <p>10 MR. KUNTZ: I guess I have to object. That's</p> <p>11 an improper hypothetical. We have asked at least 30</p> <p>12 times for that number from you guys and never been given</p> <p>13 that number. It's an impossibility for her to make the</p> <p>14 calculation.</p> <p>15 BY MS. SUTHERLAND:</p> <p>16 Q. You don't have the number?</p> <p>17 A. I don't.</p> <p>18 MR. KUNTZ: It's impossible. You won't give us</p> <p>19 that number.</p> <p>20 THE WITNESS: No.</p> <p>21 MR. KUNTZ: We have been asking for five years,</p> <p>22 is my point.</p> <p>23 BY MS. SUTHERLAND:</p> <p>24 Q. With respect to the numbers that are listed in</p> <p>25 the columns for Ethicon, do you know all of the types of</p>

13 (Pages 46 to 49)

Peggy Pence, Ph.D.

Page 50	Page 52
<p>1 events that were listed, such as erosion, pain?</p> <p>2 A. Pain, urinary tract problems.</p> <p>3 Q. Do you have a listing of what they all were for</p> <p>4 in the numbers here?</p> <p>5 A. I have -- if you go back to the TVT report and</p> <p>6 my Prolift report, there's an itemization for those</p> <p>7 specific products for the types of events as well as --</p> <p>8 Can you ask the question again?</p> <p>9 Q. Sure.</p> <p>10 For this exhibit that you put together for the</p> <p>11 supplemental report, do you have a listing of the events</p> <p>12 that are included?</p> <p>13 A. For some of the products, yes, but this is --</p> <p>14 again, I reiterate, this is a tally of all of the MDR</p> <p>15 reports that were submitted for those products. For some</p> <p>16 of these products and for certain of the years, we have</p> <p>17 done a tabulation of the numbers of erosions that were</p> <p>18 reported, the numbers of pain that were reported, the</p> <p>19 numbers of dyspareunia that were reported, the number of</p> <p>20 urinary tract issues that were reported, the number of</p> <p>21 infections that were reported. And our numbers are</p> <p>22 consistent with FDA's representation of what they</p> <p>23 reported they found in the MAUDE database, for example,</p> <p>24 in their 2008 public health notification and their update</p> <p>25 in 2011, their safety communication. And, in fact, I</p>	<p>1 MR. KUNTZ: It will help.</p> <p>2 MS. SUTHERLAND: Yes. If someone else covers</p> <p>3 it, I will definitely make sure it's squared away on what</p> <p>4 we agreed to.</p> <p>5 MR. KUNTZ: For the record, I'll have them file</p> <p>6 that in Ramirez too, if need be.</p> <p>7 MS. SUTHERLAND: If need be.</p> <p>8 BY MS. SUTHERLAND:</p> <p>9 Q. Now, let's go back to your February Prosima</p> <p>10 report.</p> <p>11 Do you need a break or anything? We have been</p> <p>12 going over an hour.</p> <p>13 A. I wouldn't mind.</p> <p>14 MS. SUTHERLAND: Let's go off the record.</p> <p>15 (Recess.)</p> <p>16 BY MS. SUTHERLAND:</p> <p>17 Q. Quickly, Pence Exhibit 2 to your Prosima</p> <p>18 February report is your CV.</p> <p>19 Is that pretty much up to date?</p> <p>20 A. Yes and no. I was looking at this the other</p> <p>21 day that I need to update the address, so the address.</p> <p>22 Q. You still have Newbury Park?</p> <p>23 A. Exactly. We do have the satellite office,</p> <p>24 basically, with my staff working remotely, but that old</p> <p>25 address is no longer accurate. I do need to update that.</p>
Page 51	Page 53
<p>1 state that in my reports where we have presented that</p> <p>2 type of information at that level of detail, that what we</p> <p>3 found for the specific products were representative of</p> <p>4 what FDA found across the numbers of manufacturers that</p> <p>5 FDA evaluated and published, for example, in its 2011</p> <p>6 review of the MAUDE database and the literature relevant</p> <p>7 to transvaginal meshes, particularly, pelvic organ</p> <p>8 prolapse for the discussion here today.</p> <p>9 Q. How long has Christine Swanson worked for you?</p> <p>10 A. Over a year, at this point, if I recall</p> <p>11 correctly.</p> <p>12 MS. SUTHERLAND: I'll hand you and attach the</p> <p>13 supplemental report for TVT.</p> <p>14 (Defendant's Exhibit 4 was marked for</p> <p>15 identification by the court reporter.)</p> <p>16 BY MS. SUTHERLAND:</p> <p>17 Q. Is that your supplemental report on TVT and</p> <p>18 TVT-O dated March 2016?</p> <p>19 A. Yes, March 2, 2016.</p> <p>20 MS. SUTHERLAND: You can set that aside. I</p> <p>21 think we're on the same page, that with the Ramirez depo</p> <p>22 coming up in a couple of weeks, that I'll address that</p> <p>23 then.</p> <p>24 MR. KUNTZ: Yes. Are you doing the depo?</p> <p>25 MS. SUTHERLAND: Unless I can get out of it.</p>	<p>1 There are a couple things to add to it. What's here is</p> <p>2 correct.</p> <p>3 Q. What are you adding to it? Presentations?</p> <p>4 A. Not presentations so much as conferences that I</p> <p>5 have attended, continuing education in my profession.</p> <p>6 There are old publications that I located to be added</p> <p>7 that I had forgotten about that I have not added.</p> <p>8 Q. Do any of those old publications have to do</p> <p>9 with pelvic mesh?</p> <p>10 A. No.</p> <p>11 Q. Do they have to do with an implanted device?</p> <p>12 A. Not to my recollection.</p> <p>13 Q. Any of the conferences that you have attended</p> <p>14 that aren't in your CV, did any of those conferences have</p> <p>15 anything to do with pelvic mesh?</p> <p>16 A. No.</p> <p>17 Q. Now, Exhibit 3 to your Prosima report is your</p> <p>18 reliance list, and I wanted to make sure on this, and</p> <p>19 Jeff, you might want to listen to this one part.</p> <p>20 MR. KUNTZ: I'm listening.</p> <p>21 THE WITNESS: Go ahead.</p> <p>22 BY MS. SUTHERLAND:</p> <p>23 Q. I didn't get any reliance lists with the</p> <p>24 supplemental reports, and I wanted to make sure that I</p> <p>25 was not supposed to get any updated reliance list with</p>

14 (Pages 50 to 53)

Peggy Pence, Ph.D.

Page 54	Page 56
<p>1 the supplemental reports in March.</p> <p>2 Do you know, Dr. Pence, and then I can talk to</p> <p>3 Jeff off the record?</p> <p>4 A. I have the information footnoted in my</p> <p>5 supplemental report. I didn't provide a reliance list</p> <p>6 additional to that.</p> <p>7 Q. I just wanted to make sure I didn't miss it if</p> <p>8 you had it.</p> <p>9 A. It's either referenced or footnoted in my</p> <p>10 report that I relied on for inclusion in the supplemental</p> <p>11 report.</p> <p>12 MR. KUNTZ: Let's off the record real quick.</p> <p>13 MS. SUTHERLAND: Okay.</p> <p>14 (Recess.)</p> <p>15 MS. SUTHERLAND: Now we're back on.</p> <p>16 BY MS. SUTHERLAND:</p> <p>17 Q. Dr. Pence, you were telling me about your CV.</p> <p>18 A. Yes. Looking at Exhibit 2, which is my CV, it</p> <p>19 looks as though this one is not the most updated version,</p> <p>20 unless I am overlooking it. Like, for example, the</p> <p>21 selected presentations, October 1, 2013, and selected</p> <p>22 continuing education, 2013 is the last listed there. And</p> <p>23 I note that in particular because you asked me about</p> <p>24 presentations, and for example, I did chair a session at</p> <p>25 the annual FDA Orange County Regulatory Affairs, OCRA</p>	<p>1 There was -- the Exhibit 2, I apologize, didn't get</p> <p>2 changed.</p> <p>3 Q. No worries. That actually helped me out</p> <p>4 because I had thought that I already asked you about this</p> <p>5 document. Apparently I have not if this was Boston</p> <p>6 Scientific.</p> <p>7 A. Some of them you had at one point asked me</p> <p>8 about part of these.</p> <p>9 Q. Just tell me real quickly, these are not all of</p> <p>10 the RCTs on prolapse repair, are they?</p> <p>11 A. No.</p> <p>12 Q. How did you --</p> <p>13 A. Not to my recollection. These were some of the</p> <p>14 key ones I identified, and I believe it's stated in my</p> <p>15 report, between 2008 and 2012.</p> <p>16 Q. When you say they're one of the key ones, were</p> <p>17 they of a certain strength or length? If you can, tell</p> <p>18 me why you denoted them as key.</p> <p>19 A. When I originally did this, it was back in</p> <p>20 2014. At this point in time, as I sit here today, I</p> <p>21 can't recall exactly why I chose these particular ones,</p> <p>22 except that, of course, they were randomized controlled</p> <p>23 trials and that, obviously, that's the highest level of</p> <p>24 evidence. Depending on the quality, it's generally</p> <p>25 considered the highest level of evidence, but you have to</p>
Page 55	Page 57
<p>1 discussion group meeting last year, that would have been</p> <p>2 2015, and I also, if I recall correctly, 2014. I think</p> <p>3 this is an older copy.</p> <p>4 Q. You think you have one that's updated?</p> <p>5 A. Yes. This is an older copy that was produced,</p> <p>6 it appears.</p> <p>7 Q. I'm sure I'll follow up with a request to Jeff</p> <p>8 to get the updated CV, and if you want to update the</p> <p>9 address and anything else that you saw, do that for me,</p> <p>10 please.</p> <p>11 A. I will do that.</p> <p>12 Q. Exhibit 5 is a listing of RCTs on prolapse</p> <p>13 repair; correct?</p> <p>14 A. Yes.</p> <p>15 Q. It says at the top, "Randomized controlled</p> <p>16 clinical trials."</p> <p>17 Did you pull this from a different report?</p> <p>18 A. Yes, and that didn't get corrected.</p> <p>19 Q. Do you know what report you might have pulled</p> <p>20 Exhibit 5 from?</p> <p>21 A. Yes.</p> <p>22 Q. I'm assuming it was Prolift?</p> <p>23 A. No. Actually, the Prolift report, if I recall</p> <p>24 correctly, only had five summarized, and in one of my BSC</p> <p>25 reports, I updated that to include all of those here.</p>	<p>1 evaluate each study individually. And because these were</p> <p>2 randomized controlled clinical trials with and without</p> <p>3 mesh, the "with and without mesh" was, of course,</p> <p>4 important to my consideration of including those in here.</p> <p>5 Q. Just so I'm clear, I don't know if I asked it</p> <p>6 this way: Are there other randomized controlled trials</p> <p>7 that are published and available with and without mesh</p> <p>8 that are not included in your Exhibit 5 or did you get</p> <p>9 them all?</p> <p>10 A. No. Yes, there are.</p> <p>11 Q. There are other additional RCTs out there on</p> <p>12 mesh and non-mesh doing a head-to-head comparison?</p> <p>13 A. Yes.</p> <p>14 Q. As you sit here today -- I know you did this a</p> <p>15 while back -- you can't tell me why you picked out these</p> <p>16 particular studies that are in here?</p> <p>17 A. I don't recall every reason that I picked those</p> <p>18 out except for what I just mentioned, because it was back</p> <p>19 in 2014, but clearly, they were randomized controlled</p> <p>20 trials, which is a high level of evidence. They were a</p> <p>21 comparison to without mesh. They were articles that I</p> <p>22 found referenced in a number of other articles, and so I</p> <p>23 thought they were representative. That would have been</p> <p>24 the standard, that they are representative of the</p> <p>25 literature at that time from 2008 to 2012.</p>

15 (Pages 54 to 57)

Peggy Pence, Ph.D.

Page 58	Page 60
<p>1 Q. As you sit here today, do you have any plans to</p> <p>2 supplement your Prosima or Prolift reports, just as you</p> <p>3 sit here today?</p> <p>4 A. As I sit here today, I don't have specific</p> <p>5 plans to supplement my report, but I reserve the right to</p> <p>6 supplement the report if needed.</p> <p>7 Q. Have you read any of the defense expert records</p> <p>8 from Wave 1 in the MDL?</p> <p>9 A. Perhaps you can clarify who those were because</p> <p>10 I don't know specifically. I have read, obviously,</p> <p>11 defense expert reports over the period of the last couple</p> <p>12 of years.</p> <p>13 Q. Let me ask it this way: Have you read any</p> <p>14 defense expert reports in the past month that were dated</p> <p>15 within the past month?</p> <p>16 MR. KUNTZ: Past week.</p> <p>17 BY MS. SUTHERLAND:</p> <p>18 Q. Past week?</p> <p>19 A. No.</p> <p>20 Q. Now, I caught myself reading your report and</p> <p>21 your exhibits. I did not see a list of testimony for the</p> <p>22 past four years.</p> <p>23 Do you have a list of testimony, both</p> <p>24 deposition and trial?</p> <p>25 A. Yes.</p>	<p>1 reports, do you know how many hours you have billed on</p> <p>2 that work?</p> <p>3 A. Repeat that again. I'm sorry.</p> <p>4 Q. What I'm trying to limit it to is the recent</p> <p>5 work you have done on Ethicon products, and as far as I</p> <p>6 know, that would be your Prosima report, your</p> <p>7 supplemental Prosima and Prolift report, and your</p> <p>8 supplemental TVT report.</p> <p>9 Do you know approximately how many hours you</p> <p>10 put into that work?</p> <p>11 A. I can tell you for the Prosima report, the</p> <p>12 February 1st, 2016, Prosima report, that I have an</p> <p>13 invoice ready to be submitted that's a little over</p> <p>14 \$34,000. I spent approximately 67 hours and Christine</p> <p>15 has over 13 hours, between 13 and 14 hours, to the best</p> <p>16 of my recollection as I sit here today. I have not</p> <p>17 totaled my time yet over the last couple of weeks for the</p> <p>18 supplemental report for TVT and Prosima and preparation</p> <p>19 for the deposition.</p> <p>20 Q. Do you have a ballpark of what you think that</p> <p>21 might be?</p> <p>22 A. As I say, I haven't totaled it. If you're</p> <p>23 including TVT, it's probably somewhere 60 to 100 hours.</p> <p>24 Without totaling it, that's my best estimate as I sit</p> <p>25 here today.</p>
Page 59	Page 61
<p>1 Q. You don't mind getting that to Jeff?</p> <p>2 A. No.</p> <p>3 Q. Along with your updated CV?</p> <p>4 A. No. In fact, I did produce that when we</p> <p>5 were -- for the February 1st Prosima report, but it</p> <p>6 wasn't provided to you then?</p> <p>7 Q. I did not see that. Was it written within your</p> <p>8 report?</p> <p>9 A. No.</p> <p>10 Q. I caught myself reading it.</p> <p>11 A. It was typed.</p> <p>12 Q. It wasn't attached to what I have seen, and I</p> <p>13 only saw the five exhibits.</p> <p>14 A. I don't include it in my report, but I did</p> <p>15 provide it to Counsel.</p> <p>16 Q. That's not a problem. We'll get it.</p> <p>17 I did not see in your report where you listed</p> <p>18 what your hourly rate is.</p> <p>19 Can you tell me what that is?</p> <p>20 A. Yes. It's \$500 an hour.</p> <p>21 Q. And is that both for testimony and review of</p> <p>22 documents?</p> <p>23 A. Yes.</p> <p>24 Q. For your Prosima report and your supplemental</p> <p>25 reports, both Prosima, Prolift, and your TVT supplemental</p>	<p>1 Q. Am I correct that you're not offering a</p> <p>2 manufacturing defect opinion for any Ethicon device?</p> <p>3 A. Can you clarify?</p> <p>4 Q. Yes. For any particular lot or batch that went</p> <p>5 through, that something went wrong in the manufacturing</p> <p>6 process. Are you offering any opinion like that for any</p> <p>7 Ethicon device?</p> <p>8 A. If you're asking me for a specific batch and</p> <p>9 manufacturing processing, as I sit here today, it's my</p> <p>10 understanding I won't be asked to offer those kinds of</p> <p>11 opinions. If you're talking about information with</p> <p>12 regard to mesh characteristics --</p> <p>13 Q. No, I'm not. I'm talking literally as it's</p> <p>14 going through the warehouse and something went wrong on</p> <p>15 the worktable going through the factory.</p> <p>16 A. That specific kind of information I have not</p> <p>17 been asked to opine on at this point in time.</p> <p>18 Q. I didn't have page numbers on your Prosima</p> <p>19 report.</p> <p>20 A. There aren't.</p> <p>21 Q. So if you'll flip over to about page 18, and</p> <p>22 what I'm looking under is, "Prosimas Development</p> <p>23 Challenges and Failures."</p> <p>24 As I understand it, you have five opinions for</p> <p>25 Prosima set out in your report; correct?</p>

16 (Pages 58 to 61)

Peggy Pence, Ph.D.

Page 62	Page 64
<p>1 A. Yes.</p> <p>2 Q. Now, obviously, you and I have talked about</p> <p>3 Prosima before?</p> <p>4 A. Yes.</p> <p>5 Q. So I'm limiting my questioning to what I have</p> <p>6 not asked you about before, at least to the best of my</p> <p>7 recollection and my review of the Cavness stip, which I</p> <p>8 will confess is quick.</p> <p>9 One thing I want to ask you about under 18,</p> <p>10 "Carey, Slack, Clinical Evaluation of Prosima Prototype,"</p> <p>11 if you're with me. Underneath there, you note, "The</p> <p>12 disclosure of certain financial interests is the standard</p> <p>13 or required practice for clinical investigators when</p> <p>14 submitting clinical study reports for publication."</p> <p>15 A. Yes.</p> <p>16 Q. Now, if I'm reading that correctly, you were</p> <p>17 not saying that this is some standard that Ethicon</p> <p>18 breached with respect to disclosure of financial</p> <p>19 interests, or are you? Maybe I should ask it that way.</p> <p>20 A. I think the answer to that is both, both the</p> <p>21 authors as well as Ethicon, because --</p> <p>22 Q. That answers the question. Let me ask the next</p> <p>23 question.</p> <p>24 Can you tell me where the standard is written</p> <p>25 that you're saying Ethicon breached with some failure to</p>	<p>1 you talking about just making a disclosure to the</p> <p>2 publication that was going to publish Dr. Carey's</p> <p>3 results?</p> <p>4 A. Well, also, it was not the financial interest.</p> <p>5 There was a poster presentation that was included. And</p> <p>6 now we're talking about FDA, but there was --</p> <p>7 Q. I'll go ahead and tell you, I really don't want</p> <p>8 to talk about FDA today, which I know surprises you and</p> <p>9 me both, but I want to focus on standards other than FDA</p> <p>10 for today.</p> <p>11 A. That's fine. Yes, there was no disclosure in</p> <p>12 the publication and, therefore, it's a matter of people</p> <p>13 reviewing, any reader reviewing an article, being able to</p> <p>14 judge the information in the article in consideration of</p> <p>15 any potential bias by virtue of one of the investigator's</p> <p>16 or more than one investigators' financial interest in a</p> <p>17 product that is being reviewed. That's the whole reason</p> <p>18 for disclosure, so that that information can be taken</p> <p>19 into account by the reviewer.</p> <p>20 Q. With publications, that information is</p> <p>21 generally provided by the investigator; correct?</p> <p>22 A. That is correct. However, Ethicon was very</p> <p>23 heavily involved in the development of this information.</p> <p>24 In fact, you will note that on page 20 in the report -- I</p> <p>25 realize there are no page numbers there -- but page 20,</p>
Page 63	Page 65
<p>1 disclose financial interest?</p> <p>2 A. Yes. Publications, generally, expect any</p> <p>3 disclosure of financial or proprietary interest to be</p> <p>4 disclosed. The FDA 21 CFR Part 54 on financial</p> <p>5 disclosures, an FDA regulation -- and give me just a</p> <p>6 moment.</p> <p>7 Q. Are you looking for the standard?</p> <p>8 A. Yes.</p> <p>9 Q. Are you thinking it's something besides the FDA</p> <p>10 standard that we talked about?</p> <p>11 A. Yes. To the best of my recollection,</p> <p>12 disclosure of proprietary and financial interest is also</p> <p>13 included in international standards, whether it's GHTF or</p> <p>14 ISO, to the best of my recollection as I sit here today.</p> <p>15 Q. You didn't cite any ISO standards in any of</p> <p>16 your Prosima reports that I saw, did you?</p> <p>17 A. No. If you look at the GHTF documents, a</p> <p>18 number of them do have, in the reference documents, ISO</p> <p>19 standards.</p> <p>20 Q. Do you know which GHTF document you're talking</p> <p>21 about that might have the standard to disclose financial</p> <p>22 interest?</p> <p>23 A. Not to the best of my recollection sitting here</p> <p>24 today. I would have to double check that.</p> <p>25 Q. The disclosure that you're talking about, are</p>	<p>1 that Dr. Robinson noted that BJOG had agreed to publish</p> <p>2 Carey's study, but that it would require a major rewrite.</p> <p>3 And Dr. Robinson, reflecting on the internal team's</p> <p>4 concerns about the large number of patients lost to</p> <p>5 follow up, and that Dr. Carey had submitted the draft</p> <p>6 manuscript without Ethicon's review, remarked, "This</p> <p>7 seems the best of both worlds. We get the chance to</p> <p>8 revise the data, Marcus's wishes to work with the</p> <p>9 clinical team here in developing the manuscript, and we</p> <p>10 have the agreement from the journal that they will</p> <p>11 publish once they are happy with the manuscript."</p> <p>12 Ethicon definitely had involvement.</p> <p>13 Q. I want to be sure that I know the extent of</p> <p>14 your opinion. Is the financial disclosure that you're</p> <p>15 talking about something that should have been made to</p> <p>16 BJOG?</p> <p>17 A. Yes.</p> <p>18 Q. If I'm reading your report correctly --</p> <p>19 A. If we're excluding FDA for this discussion. It</p> <p>20 should have been made to FDA with the poster presentation</p> <p>21 presented to FDA. If we're excluding FDA, then yes.</p> <p>22 Q. Now, the disclosure that we're talking about</p> <p>23 that should have been made to BJOG was the amount paid to</p> <p>24 Dr. Carey?</p> <p>25 A. It should have been that he had a financial</p>

17 (Pages 62 to 65)

Peggy Pence, Ph.D.

Page 66	Page 68
<p>1 interest, a consulting relationship, and that the product</p> <p>2 had been licensed, that he had a proprietary interest in</p> <p>3 the development of the product.</p> <p>4 Q. It's your understanding that was not done?</p> <p>5 A. Correct. I did not find that the published</p> <p>6 paper included any disclosure of his financial interest</p> <p>7 or Ethicon's involvement.</p> <p>8 Q. Do you know if that information was provided to</p> <p>9 BJOG otherwise? You know, the publication sends their</p> <p>10 conflict of interest document that goes with the</p> <p>11 publication itself. Do you know if disclosure was made</p> <p>12 to BJOG but was not included in the published report?</p> <p>13 A. As I sit here today, I don't recall having seen</p> <p>14 that.</p> <p>15 Q. Let me turn over to your first opinion that's</p> <p>16 listed in the report, which is on page 32. I'm going to</p> <p>17 try to cut through this.</p> <p>18 As I understand it, this opinion focuses on</p> <p>19 what -- your opinion was not provided to FDA, and had FDA</p> <p>20 known certain things, it would not have cleared Prosima.</p> <p>21 Is that a fair nutshell?</p> <p>22 A. As I understand your question, yes.</p> <p>23 Q. Let's go to Opinion 2, which is, as I</p> <p>24 understand it -- let me ask you this: For Opinion 2, if</p> <p>25 I'm understanding, is it your opinion that there were</p>	<p>1 two-thirds of the way down in that paragraph, you say,</p> <p>2 "There Ethicon failed to follow the requirement it</p> <p>3 created for releasing the Prosima onto the market. If</p> <p>4 Ethicon had followed its own internal requirement related</p> <p>5 to safety and performance of the Prosima, it never would</p> <p>6 have been released."</p> <p>7 A. Right.</p> <p>8 Q. The question to you is: What internal</p> <p>9 requirement of Ethicon are we talking about there, just</p> <p>10 so I know?</p> <p>11 A. It was the project charter, and it is</p> <p>12 referenced in my report. Let me just locate it. It's on</p> <p>13 page 18 of the report, at the very end of the paragraph</p> <p>14 at the top of the page, "Importantly at the outset of the</p> <p>15 Project Mint charter."</p> <p>16 Q. I'm not with you yet. I think I'm on 18.</p> <p>17 A. Middle of the page, it has Section B, "Prosimas</p> <p>18 development challenges and failures." At the top of that</p> <p>19 page, the last sentence of that paragraph, "Importantly</p> <p>20 at the outset of the Project Mint charter," which was</p> <p>21 Prosima, for Prosima, what became Prosima, I should say,</p> <p>22 "Ethicon recognized that if the results of the clinical</p> <p>23 evaluation performed by the inventor, Dr. Marcus Carey,</p> <p>24 and his development partner, Dr. Mark Slack of Cambridge,</p> <p>25 United Kingdom, were not favorable, the project should be</p>
Page 67	Page 69
<p>1 inadequate studies, clinical studies, to support the</p> <p>2 marketing of Prosima? Is that part of your Opinion 2?</p> <p>3 A. That is part of my Opinion 2, yes.</p> <p>4 Q. Is the second half of your Opinion 2 that after</p> <p>5 Prosima was marketed, there remained a lack of clinical</p> <p>6 studies showing its safety and efficacy? And I'll tell</p> <p>7 you what I'm trying to do here is have a dividing line</p> <p>8 between premarket and postmarket if we can do that with</p> <p>9 your opinion.</p> <p>10 A. Give me one moment. Can you repeat your</p> <p>11 question, please?</p> <p>12 Q. Yes, ma'am.</p> <p>13 If I'm understanding your Opinion 2 correctly,</p> <p>14 does it cover both premarket studies, which, in your</p> <p>15 opinion, did not show safety and efficacy of Prosima, and</p> <p>16 postmarket studies, which did not show safety and</p> <p>17 efficacy of Prosima?</p> <p>18 A. Yes.</p> <p>19 Q. So let me try to address those in two separate</p> <p>20 buckets, if I could, just to keep things clear. You and</p> <p>21 I have already talked about the studies that were</p> <p>22 conducted back in Cavness. Really, what I'm focusing on</p> <p>23 here are the standards that you're relying on for your</p> <p>24 opinions.</p> <p>25 The first question I want to ask you is, about</p>	<p>1 abandoned or the scope changed."</p> <p>2 Q. And you reference there Footnote 40?</p> <p>3 A. Yes.</p> <p>4 Q. Is Footnote 40 the document that supports that</p> <p>5 sentence?</p> <p>6 A. Yes, Project Mint charter presentation from</p> <p>7 June of 2005.</p> <p>8 Q. We go on -- and I'm back at page 33 -- "For all</p> <p>9 medical devices, the internationally accepted standard of</p> <p>10 care is that a clinical evaluation of the device,</p> <p>11 including clinical data, show a favorable benefit-risk</p> <p>12 ratio."</p> <p>13 A. Correct.</p> <p>14 Q. Now, where is that internationally accepted</p> <p>15 standard of care written?</p> <p>16 A. It's repeated in a variety of documents, but if</p> <p>17 you look at Exhibit 1 in the supplemental report and you</p> <p>18 go to the essential principles of safety and performance,</p> <p>19 for example, to page 3 in that Exhibit 1 of the</p> <p>20 supplemental report, one of the principles in essential</p> <p>21 principles of safety and performance -- let me start on</p> <p>22 the prior page, on page 2, with the very first essential</p> <p>23 principle of safety and performance that's listed.</p> <p>24 "Medical devices should be designed and manufactured in</p> <p>25 such a way that, when used under the conditions and for</p>

18 (Pages 66 to 69)

Peggy Pence, Ph.D.

Page 70	Page 72
<p>1 the purposes intended and where applicable, by virtue of</p> <p>2 the technical knowledge, experience, education or</p> <p>3 training, and the medical and physical conditions of</p> <p>4 intended users, they will perform as intended by the</p> <p>5 manufacturer and not compromise the clinical condition or</p> <p>6 the safety of patients, provided that any risk which may</p> <p>7 be associated with their use constitute acceptable risk</p> <p>8 when weighed against the benefits to the patient and are</p> <p>9 compatible with a high level of protection of health and</p> <p>10 safety."</p> <p>11 Q. Where does that come from?</p> <p>12 A. This comes from the final document, Global</p> <p>13 Harmonization Task Force, Essential Principles of Safety</p> <p>14 and Performance of Medical Devices.</p> <p>15 Q. That's what I'm going to hand you, Exhibit 10.</p> <p>16 (Defendant's Exhibit 10 was marked for</p> <p>17 identification by the court reporter.)</p> <p>18 BY MS. SUTHERLAND:</p> <p>19 Q. Is that a document that sets out the standard</p> <p>20 that you reference back in your report on page 33? What</p> <p>21 I want to do is I want to get what all of the standards</p> <p>22 are. If I have questions about those, I'll come back.</p> <p>23 A. Repeat the last question.</p> <p>24 Q. Yes, ma'am.</p> <p>25 I'm back on page 33. What I'd asked you there</p>	<p>1 which I have marked as Number 10; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And then you said there are other GHTF guidance</p> <p>4 documents that also have that same standard?</p> <p>5 A. Well, they reference back to the essential</p> <p>6 principles of safety and performance, which include a</p> <p>7 favorable benefit risk. For example, if you go to the</p> <p>8 clinical evaluation, May 2007.</p> <p>9 Q. You got to slow down. I want to get them all.</p> <p>10 Tell what that was, May 2007 clinical evaluation?</p> <p>11 A. May 2007, yes.</p> <p>12 MS. SUTHERLAND: I'll mark that as Number 11.</p> <p>13 I am not going to have all of these. I tried to get all</p> <p>14 of them that I could.</p> <p>15 (Defendant's Exhibit 11 was marked for</p> <p>16 identification by the court reporter.)</p> <p>17 BY MS. SUTHERLAND:</p> <p>18 Q. I'm handing you what I marked as Number 11.</p> <p>19 Is that the second standard that you were just</p> <p>20 discussing?</p> <p>21 A. Yes.</p> <p>22 Q. Now, is there another one?</p> <p>23 A. For example, in the document -- this is the</p> <p>24 point I'm trying to make -- the GHTF documents represent</p> <p>25 a global model that has been accepted internationally for</p>
Page 71	Page 73
<p>1 was, you reference an internationally accepted standard</p> <p>2 of care in that bottom part of that paragraph.</p> <p>3 A. Yes.</p> <p>4 Q. My question to you is: Is that internationally</p> <p>5 accepted standard of care that you're referencing</p> <p>6 contained in what I have now marked as Deposition Exhibit</p> <p>7 Number 10?</p> <p>8 A. It is contained in here, and also, the</p> <p>9 risk-benefit information is also. The need for favorable</p> <p>10 benefit-risk assessment for marketing of a medical device</p> <p>11 is also referenced in other standards, other GHTF</p> <p>12 standards.</p> <p>13 Q. What are those?</p> <p>14 A. For example, the --</p> <p>15 Q. Put a pin in that and we'll come back to that.</p> <p>16 For the sentence that you have got written here</p> <p>17 on page 33 which talks about, "For all medical devices,</p> <p>18 the internationally accepted standard of care is that a</p> <p>19 clinical evaluation of the device, including clinical</p> <p>20 data in the form of clinical studies, literature,</p> <p>21 clinical experience, must demonstrate that a favorable</p> <p>22 benefit-risk ratio exists for the device."</p> <p>23 For that sentence, you're saying you look to</p> <p>24 that standard which is contained in GHTF, Essential</p> <p>25 Principles of Safety and Performance of Medical Devices,</p>	<p>1 the development of medical devices. For example, if you</p> <p>2 start with the essential principles of safety and</p> <p>3 performance, if you look at the clinical evaluation</p> <p>4 document, Exhibit 11, if you look on page 6, you'll see,</p> <p>5 under the references, that this document references the</p> <p>6 essential principles of safety and performance of medical</p> <p>7 devices. Now, Exhibit 10 happens to be the 2012 update</p> <p>8 to a 2005 document on essential principles of safety and</p> <p>9 performance. So you'll see, because the clinical</p> <p>10 evaluation document was May of 2007, that the essential</p> <p>11 principles of safety and performance document that it</p> <p>12 references was the 2005 document.</p> <p>13 There were updates to these documents over the</p> <p>14 period of the 20 years of the existence of the GHTF, but</p> <p>15 there's an interrelationship between these documents that</p> <p>16 support one another in creating this model for a global</p> <p>17 clinical development. These various standards support</p> <p>18 the efforts that need to be undertaken to demonstrate</p> <p>19 conformity to the essential principles of safety and</p> <p>20 performance.</p> <p>21 So you'll see in this clinical evaluation,</p> <p>22 Exhibit 11, that one of the documents it references is</p> <p>23 also the principles of conformity assessment for medical</p> <p>24 devices, which is another standard, and that that</p> <p>25 standard also references back to the essential principles</p>

19 (Pages 70 to 73)

Peggy Pence, Ph.D.

Page 74	Page 76
<p>1 of safety and performance.</p> <p>2 Q. Did you go back and review the 2005 essential</p> <p>3 principles?</p> <p>4 A. Yes, I certainly have.</p> <p>5 Q. Did you do that for your opinion in this case?</p> <p>6 A. To the best of my recollection, I did, yes.</p> <p>7 Q. Do you know what the differences are between</p> <p>8 the 2005 version and the 2012 version?</p> <p>9 A. If I recall correctly, if I'm not confusing the</p> <p>10 standards, one of the key differences was the inclusion</p> <p>11 of information relative to in vitro diagnostic devices.</p> <p>12 Q. I'm asking you that based on your phrasing here</p> <p>13 on page 33 where you say, "For all medical devices, the</p> <p>14 internationally accepted standard of care is that a</p> <p>15 clinical evaluation of the device includes clinical data</p> <p>16 in the form of clinical studies."</p> <p>17 My question to you is: Is it your opinion that</p> <p>18 all medical devices require clinical data in order to</p> <p>19 have an analysis of the benefit-risk ratio?</p> <p>20 A. I think I need clarification. Can you point me</p> <p>21 again to the statement you're referencing?</p> <p>22 Q. Down on page 33, the sentence we have been</p> <p>23 talking about, where it says, "For all medical devices."</p> <p>24 It starts over on the left-hand side.</p> <p>25 A. I have it.</p>	<p>1 devices, because we're talking about devices that have</p> <p>2 been marketed based on similarity to previously marketed</p> <p>3 devices, the standard allows you to evaluate the</p> <p>4 literature for similar devices or commercial experience.</p> <p>5 Hence, that goes to why I looked at the MDR database</p> <p>6 because that's publicly available information that a</p> <p>7 manufacturer can look at for competitor products that are</p> <p>8 similar to look at the clinical experience.</p> <p>9 If looking at that totality of information that</p> <p>10 is available, one can rely on that based on comparing</p> <p>11 one's own device to the other devices that are</p> <p>12 represented in that, when we're talking about a brand-new</p> <p>13 device. If the manufacturer can substantiate, based on</p> <p>14 that available information, that there's a favorable</p> <p>15 benefit-risk ratio, then premarket clinical studies may</p> <p>16 not be required. Based on distinctions between your</p> <p>17 device and similar devices --</p> <p>18 Q. I think you answered the question.</p> <p>19 A. -- then clinical studies may be required. As I</p> <p>20 have testified to before -- I just need to answer this to</p> <p>21 be complete --</p> <p>22 Q. It sounded pretty complete.</p> <p>23 A. -- then the company has to make a determination</p> <p>24 that they may need to do clinical studies in order to</p> <p>25 show that there's a favorable benefit-to-risk ratio.</p>
Page 75	Page 77
<p>1 Q. That's the sentence I'm focusing on.</p> <p>2 A. Yes.</p> <p>3 Q. My question is, if I'm reading that sentence,</p> <p>4 it reads to me that your opinion is that all medical</p> <p>5 devices require clinical data, meaning in human use, to</p> <p>6 have an analysis of the benefit-risk ratio.</p> <p>7 Is that your opinion?</p> <p>8 A. That's what's stated in the standard, but</p> <p>9 clinical data can be in the form of scientific medical</p> <p>10 literature and commercial experience as well as clinical</p> <p>11 studies.</p> <p>12 Q. So for a new device that's coming out where you</p> <p>13 don't have published medical literature yet and you don't</p> <p>14 have previous clinical experience because it's a new</p> <p>15 device, am I understanding your opinion to be that the</p> <p>16 standard that you're referencing from GHTF is that you</p> <p>17 have to have a clinical trial in order to analyze that</p> <p>18 benefit-risk ratio?</p> <p>19 A. No, that's not what the standard says. In</p> <p>20 analyzing the benefit-to-risk ratio, because we're</p> <p>21 talking for Class II devices --</p> <p>22 Q. Correct, at least at the time.</p> <p>23 A. We were talking about Class II devices, and</p> <p>24 then, of course, Class III devices now that they have</p> <p>25 been reclassified to high risk, but for medium risk</p>	<p>1 Q. I think I can get this as a yes or no.</p> <p>2 Am I correct, Dr. Pence, that the GHTF</p> <p>3 standards that you and I have talked about don't set out</p> <p>4 a bright-line rule saying for all medical devices, you</p> <p>5 have to have clinical data, meaning trials in humans,</p> <p>6 before you may analyze the benefit-to-risk ratio?</p> <p>7 MR. KUNTZ: Objection to form.</p> <p>8 THE WITNESS: As you stated that, I can't give</p> <p>9 you yes or no because the clinical data includes --</p> <p>10 doesn't include just clinical investigations on a</p> <p>11 specific device.</p> <p>12 BY MS. SUTHERLAND:</p> <p>13 Q. For my purposes for this question, when I'm</p> <p>14 talking about clinical data, I'm talking about the</p> <p>15 company that has the device that they want to market</p> <p>16 running a clinical trial in humans.</p> <p>17 A. If you're talking about running a clinical</p> <p>18 trial in humans specifically, if -- again, it's very</p> <p>19 qualified. One has to do this on an individual device</p> <p>20 basis to decide whether or not your device -- if other</p> <p>21 devices for which there is data or which there are data,</p> <p>22 either in terms of commercial experience and literature,</p> <p>23 if those data are adequate to substantiate a favorable</p> <p>24 benefit-risk ratio for your device, considering the</p> <p>25 differences of your device to those devices on which</p>

20 (Pages 74 to 77)

Peggy Pence, Ph.D.

Page 78	Page 80
<p>1 information is available, if you can substantiate a 2 favorable benefit-risk ratio based on such evidence, then 3 you would not have to do clinical trials. But if you 4 can't, then you need to do clinical studies to 5 demonstrate a favorable benefit-risk ratio.</p> <p>6 Q. So no bright-line rule from the GHTF documents 7 saying you always have to run a clinical trial before you 8 can sell a device?</p> <p>9 A. It's a case-by-case basis depending on the 10 differences in the device and whether the information 11 that is already available for other devices or maybe a 12 prior device, and your device is a modification of the 13 prior device, whether the information is --</p> <p>14 Q. It really is yes or no.</p> <p>15 There's no bright-line rule from the GHTF 16 documents you and I have talked about saying you always 17 have to run a clinical trial in humans before you can 18 evaluate the benefit-risk ratio, yes or no?</p> <p>19 MR. KUNTZ: Objection. Asked and answered.</p> <p>20 THE WITNESS: For the reasons I have mentioned 21 you have to evaluate, no, you have to evaluate on an 22 individual basis, case by case.</p> <p>23 BY MS. SUTHERLAND:</p> <p>24 Q. I think we got our yeses and nos mixed up 25 there. Let me try one last time.</p>	<p>1 what I'm looking for. Does that standard set out the 2 size of the clinical trial a manufacturer would have to 3 do?</p> <p>4 A. That's based on statistics. It gives you the 5 principles, and it gives additional references as well, 6 but it gives you the principles for doing a clinical 7 investigation, and it also references other international 8 standards. I mentioned ISO standards and GHTF standards, 9 also referenced ISO standards, and in this document, for 10 example, on page 5, it references ISO 14155-1 and ISO 11 14155-2, both 2003 documents.</p> <p>12 Q. Do those set out the size? Is there something 13 seriously a manufacturer can look at that says I need 50 14 people? 150 people?</p> <p>15 A. That's based on statistics. When you're 16 designing a clinical trial, the standards say you set out 17 your end points, your objectives. And when you're 18 designing a clinical trial, you make a decision as to 19 what kind of a different -- if you're doing a comparison.</p> <p>20 Q. Is it a case-by-case decision, essentially?</p> <p>21 A. Yes, it is, based on what your end point is 22 going to be, and then the statistician determines how 23 many patients need to be included in each arm.</p> <p>24 Q. Is it also a case-by-case decision as to how 25 long you need your study to go?</p>
Page 79	Page 81
<p>1 There is no bright-line rule in the GHTF 2 documents that you and I have talked about saying that a 3 manufacturer always has to run clinical trials in humans 4 before that manufacturer can adequately assess the 5 benefit-risk-ratio; right?</p> <p>6 A. As I understand your question, right, there is 7 no bright-line rule because every product is different, 8 but the bright-line rule is that you must be able to 9 demonstrate a favorable benefit-risk ratio on available 10 evidence.</p> <p>11 Q. You answered my question. I got it.</p> <p>12 Is there a standard that a manufacturer can go 13 to to tell them, if they think they need to run a 14 clinical trial, how to set it up: How many people need 15 to be in it, how long does it need to be, what end 16 points? Is there some written standard that a 17 manufacturer can go to that sets that out for them?</p> <p>18 A. That sets out the foundation, yes. One is the 19 GHTF clinical investigations.</p> <p>20 Q. What standard is that, clinical investigations?</p> <p>21 A. It's in Exhibit 8 under the tab, "Clinical 22 investigations." The title of the document is, "Clinical 23 Investigations," authored by Study Group 5 of the Global 24 Harmonization Task Force, February 12th, 2010.</p> <p>25 Q. For instance, let me give you an example of</p>	<p>1 A. Yes. It depends on the medical device. If 2 you're doing an ocular treatment that's an eye drop, you 3 don't need to follow those patients for their lifetime, 4 for example. If you're doing a permanent implant and a 5 registry study, for example, you would want to follow 6 them as long as possible so you have long-term data. 7 It's very dependent on the product.</p> <p>8 Q. For a permanent implant that a manufacturer 9 would like to get marketed before the passage of a 10 generation of people, is there some sort of standard that 11 sets out how long a clinical trial would need to go to 12 adequately assess the benefit-risk ratio?</p> <p>13 A. There are authoritative bodies that have 14 provided that information with regard to permanent 15 implants.</p> <p>16 Q. Is that a standard I can look at? You're 17 turning to the supplemental report?</p> <p>18 A. I am.</p> <p>19 Q. Exhibit 1?</p> <p>20 A. Yes. I do talk about implantable devices more 21 in the context of labeling in Exhibit 1.</p> <p>22 Can you repeat the question?</p> <p>23 Q. Yes, ma'am. I was wondering is there a 24 standard that sets out a general length of time that a 25 manufacturer who is making a permanent implant would need</p>

21 (Pages 78 to 81)

Peggy Pence, Ph.D.

Page 82	Page 84
<p>1 to have follow-up before they can make an analysis of the</p> <p>2 benefit-risk ratio before marketing? Is there a standard</p> <p>3 that sets that out for a permanent implant?</p> <p>4 A. As I sit here today, I don't recall having seen</p> <p>5 a standard that specifically sets out prior to marketing.</p> <p>6 Again, it depends on a favorable benefit-risk ratio. It</p> <p>7 depends on whether alternative treatments are available.</p> <p>8 It's the kind of information that, prior to marketing, a</p> <p>9 company works out with the regulators. If you look --</p> <p>10 Q. I think you answered my question.</p> <p>11 A. I just want to be complete. If you look at</p> <p>12 what's -- at minimum a year for short term. If you look</p> <p>13 at what authoritative bodies are looking at for medium</p> <p>14 term or long term, it's three to five for medium term and</p> <p>15 beyond five years for long term.</p> <p>16 Q. Is that FDA that you're talking about that</p> <p>17 refers to medium term as three to five years and long</p> <p>18 term as five years or more?</p> <p>19 A. It's not just FDA. It's some of the other</p> <p>20 authoritative bodies that have looked at information.</p> <p>21 For example, I believe it's -- I want to say it's NICE,</p> <p>22 but I have to double check my memory --</p> <p>23 Q. I think you answered the question.</p> <p>24 A. -- that talks about medium is five years and</p> <p>25 long term is ten years. But it's information that a</p>	<p>1 A. Yes.</p> <p>2 Q. With respect to --</p> <p>3 A. If asked, I will.</p> <p>4 Q. If asked, you will.</p> <p>5 With respect to that opinion, do you intend to</p> <p>6 offer an opinion as to how many women should have been</p> <p>7 enrolled in that study?</p> <p>8 A. Not a specific number of women, no, because I</p> <p>9 would need to involve a statistician to write out the</p> <p>10 protocol and the end points.</p> <p>11 Q. That would be a no?</p> <p>12 A. I'd need to provide that to a statistician to</p> <p>13 give me the numbers that we needed to demonstrate the</p> <p>14 safety and efficacy end points that we've set out as</p> <p>15 objectives in the protocol.</p> <p>16 Q. The question was, do you intend to offer an</p> <p>17 opinion as to the number of women that should have been</p> <p>18 in a clinical trial for Prosima prelaunch, I think the</p> <p>19 answer was no?</p> <p>20 A. The answer would be an adequate number to</p> <p>21 demonstrate safety and performance as outlined in the</p> <p>22 protocol.</p> <p>23 Q. Do you have a number that you intend to offer</p> <p>24 to a jury that should have been in some clinical trial</p> <p>25 before launch?</p>
Page 83	Page 85
<p>1 manufacturer works out with the body that's going to give</p> <p>2 it authorization to market the product --</p> <p>3 Q. And here in the U.S., that would be the FDA?</p> <p>4 A. That would be the FDA here in the U.S.</p> <p>5 -- and then makes a commitment, if that</p> <p>6 authoritative body that provides authorization for</p> <p>7 marketing allows them to market on one-year data or</p> <p>8 two-year data, and that's going to also be dependent on</p> <p>9 what the results are for that period of time.</p> <p>10 Q. I think you answered the question.</p> <p>11 A. But it will be with the commitment to continue</p> <p>12 following patients for a certain period of time based on</p> <p>13 working that out with the authoritative body that</p> <p>14 provides authorization for marketing.</p> <p>15 Q. When was Prosima put on the market?</p> <p>16 A. Various documentation, if I recall correctly,</p> <p>17 shows around December of 2009, some show 2010, but in</p> <p>18 that time frame.</p> <p>19 Q. Now, are you intending to opine to a jury --</p> <p>20 let me address this just with Prosima first off. Are you</p> <p>21 intending to opine to a jury that a specific clinical</p> <p>22 trial should have been conducted on Prosima before it was</p> <p>23 marketed?</p> <p>24 A. Yes.</p> <p>25 Q. You have answered my question.</p>	<p>1 A. Without designing the protocol and doing the</p> <p>2 appropriate statistics to come up with the right number</p> <p>3 to demonstrate safety and effectiveness based on the end</p> <p>4 points of the trial, I can't give you a specific number.</p> <p>5 Q. You haven't drafted a protocol to that end,</p> <p>6 have you, for Prosima?</p> <p>7 A. No, I have not.</p> <p>8 Q. Do you intend to, as you sit here today?</p> <p>9 A. If I were asked to do that, I would. I have</p> <p>10 not been asked to do that at this point in time.</p> <p>11 Q. Having not been asked to do that, you don't</p> <p>12 intend to do that right now out of the goodness of your</p> <p>13 heart, do you?</p> <p>14 A. That's currently not my plan, as I sit here</p> <p>15 today.</p> <p>16 Q. I have maybe 15 more minutes, so let me get to</p> <p>17 another opinion. If we can turn to your opinion on</p> <p>18 labeling. Go back to your full Prosima report. I'm on</p> <p>19 page 41 and 42, do you see that, Opinion 3 and 4.</p> <p>20 The first thing I want to do is what I did</p> <p>21 before. For your opinion in Number 3 with respect to</p> <p>22 looking at that first paragraph. And underneath there,</p> <p>23 about halfway down the first paragraph, you say, "The</p> <p>24 globally recognized industry standard for prescription</p> <p>25 devices, such as Prosima, is for the product IFU to</p>

22 (Pages 82 to 85)

Peggy Pence, Ph.D.

Page 86	Page 88
<p>1 contain information necessary," and you go on.</p> <p>2 A. Yes.</p> <p>3 Q. Now, that Footnote 146 references the GHTF</p> <p>4 label and instructions for use document; correct?</p> <p>5 A. Correct.</p> <p>6 Q. You wrote that it supersedes previous version</p> <p>7 in June 2005?</p> <p>8 A. Yes.</p> <p>9 Q. Now, is that document that's referenced in 146</p> <p>10 where the globally recognized industry standard is set</p> <p>11 out that you reference here in Opinion 3?</p> <p>12 A. Yes.</p> <p>13 MS. SUTHERLAND: Let me unload another</p> <p>14 document. I'm going to hand you what I have marked as</p> <p>15 Number 12.</p> <p>16 (Defendant's Exhibit 12 was marked for</p> <p>17 identification by the court reporter.)</p> <p>18 BY MS. SUTHERLAND:</p> <p>19 Q. Am I handing you as Number 12 the documents</p> <p>20 referenced in Footnote 146?</p> <p>21 A. Yes.</p> <p>22 Q. Now, other than what I have just handed you,</p> <p>23 the GHTF document from 2011 (superseding 2005) is there</p> <p>24 another document that you're referring to there that sets</p> <p>25 out any kind of labeling standard on which you rely on</p>	<p>1 listed. That's obviously been updated. I wanted you to</p> <p>2 know that there were prior standards that didn't just</p> <p>3 happen in 2011 and 2005. I did include that.</p> <p>4 Q. Are you telling me that, to some extent,</p> <p>5 because you read Judge Goodwin's order on the relevancy</p> <p>6 of documents that came out after a device had been</p> <p>7 marketed?</p> <p>8 A. I'm telling you that because any time documents</p> <p>9 are predated by other documents, one has to incorporate</p> <p>10 by reference those prior documents.</p> <p>11 Q. Does it not have anything to do with Judge</p> <p>12 Goodwin's order?</p> <p>13 A. I did see that in the order, yes, but my</p> <p>14 typical practice is to be comprehensive. And you'll</p> <p>15 notice that in prior documents that I have referenced SOP</p> <p>16 documents that were superseded prior to ever reading</p> <p>17 that.</p> <p>18 With regard to the rest of the question about</p> <p>19 is this the sole document I rely on, again, as I</p> <p>20 described earlier, the interrelationship between these</p> <p>21 documents. And for example, if you look at Exhibit 10,</p> <p>22 "The Essential Principles of Safety and Performance of</p> <p>23 Medical Devices," and you look at the table of contents,</p> <p>24 B 13 under Section 7 is label and instructions for use.</p> <p>25 These documents, as I mentioned, are interrelated. If</p>
Page 87	Page 89
<p>1 for your opinion?</p> <p>2 MR. KUNTZ: I'm going to object. It's vague.</p> <p>3 BY MS. SUTHERLAND:</p> <p>4 Q. I can rephrase if you didn't understand.</p> <p>5 MR. KUNTZ: Related to just the GHTF or all</p> <p>6 documents?</p> <p>7 BY MS. SUTHERLAND:</p> <p>8 Q. My question was a document that sets out the</p> <p>9 standard in addition to what we have already marked, is</p> <p>10 there another document that I can look at that sets out</p> <p>11 the standard for labeling for which you're relying on for</p> <p>12 your opinion contained in Number 3?</p> <p>13 A. I want to look up something for a moment, but I</p> <p>14 want to say that the initial labeling for medical devices</p> <p>15 standard that predated the 2011 and the 2005 was in</p> <p>16 February of 2000, and it is included in the binder of</p> <p>17 GHTF final documents.</p> <p>18 Q. Was that the first one?</p> <p>19 A. To the best of my recollection. That's to the</p> <p>20 best of my recollection, yes.</p> <p>21 Q. TVT came out before that, didn't it?</p> <p>22 A. Yes, it did. I'm just trying to think back.</p> <p>23 When I told you about current documents, I did include in</p> <p>24 the binder GHTF documents, some of the predate documents,</p> <p>25 and I'd have to double check whether the 2000 is still</p>	<p>1 you look at the reference page in that Exhibit 10 on</p> <p>2 essential principles of safety and performance, you'll</p> <p>3 see that one of the reference documents is the label and</p> <p>4 instructions for use for medical devices.</p> <p>5 Additionally, if you look in what's Exhibit 8,</p> <p>6 the second tab, the guidance document, principles of</p> <p>7 conformity assessment for medical devices, you will see</p> <p>8 that in the documents referenced there, the label</p> <p>9 instructions for use for medical devices is included.</p> <p>10 Again, if you look under the third tab also in</p> <p>11 Exhibit 8, the summary technical documentation for</p> <p>12 demonstrating conformity to the essential principles of</p> <p>13 safety and conformance of medical devices (STED), you</p> <p>14 will see, also, that -- in this case, it references the</p> <p>15 2005 document, labeling for medical devices is</p> <p>16 referenced.</p> <p>17 Q. Multiple documents is what you're telling me?</p> <p>18 A. Multiple documents, yes.</p> <p>19 Q. Let me ask you this: You and I have talked</p> <p>20 before about the blue book memo from 1991; right?</p> <p>21 A. Yes.</p> <p>22 Q. And as I understand it, that sets out a</p> <p>23 standard that you warn of risks that are associated with</p> <p>24 the device; correct?</p> <p>25 A. Yes.</p>

23 (Pages 86 to 89)

Peggy Pence, Ph.D.

Page 90	Page 92
<p>1 Q. Now, is there a similar standard setting out 2 what risks you need to warn about in those GHTF documents 3 that you told me? 4 A. Yes, and it's stated in my report. If you look 5 at Exhibit 1 to the supplemental report, at the bottom of 6 page 5, there's a discussion on labeling. 7 If you see at the top of page 6, the standard 8 is that instructions for use should include any residual 9 risk. And importantly, risk is defined as the 10 probability of occurrence of the risk -- a combination of 11 the probability of occurrence of the risk and the 12 severity of the risk. Instructions for use should 13 include any residual risk, warnings, precautions, 14 limitations, or contraindications and measures to be 15 taken. The information included in the instructions for 16 use should be consistent with available clinical data, 17 and all the hazards -- emphasis on all -- all the hazards 18 and other clinically relevant information should be 19 identified appropriately. Any expected and foreseeable 20 side effects, including information to be provided to the 21 patient, should be included in the instructions for use, 22 and any residual risk identified in a risk analysis 23 should be reflected as contraindications or warnings 24 within the labeling. 25 Q. Now, would you agree with me that -- you have</p>	<p>1 than with mesh, to correct prolapse; correct? 2 A. Yes. 3 Q. Surgeries, other than with mesh; right? 4 A. Yes. 5 Q. Now, are you familiar enough with those other 6 surgeries to tell me which of the risks listed here in 7 this first section, from hematoma to procedure failure, 8 you do not have if you don't use mesh? 9 A. That you do not have? 10 Q. Right. Are there any risks there listed that 11 you don't have if you don't use mesh? 12 A. Contracture of the mesh itself. 13 Q. Any other ones that you do not have if you 14 don't use mesh? 15 MR. KUNTZ: I'm going to object as vague as to 16 postoperative or long-term. 17 THE WITNESS: In fact, I was just going to say 18 what you have to consider here is not only -- I have 19 pointed that out in multiple reports, not only whether or 20 not they occur with other procedures, but the difference 21 in the frequency of occurrence and the severity of 22 occurrence, the permanency of the occurrence. 23 BY MS. SUTHERLAND: 24 Q. I'll get to that. Right now the only question 25 is -- and I think you answered that -- just out of the</p>
Page 91	Page 93
<p>1 risks associated with just surgery itself, and then you 2 have risks associated with the use of the device. 3 Are you following me? 4 A. Yes. 5 Q. Turn to page 35 and 36 of your original Prosima 6 report. 7 A. Yes. 8 Q. Yours looks different than mine. 9 A. I'm sorry. 10 Q. I know we're talking about prolapse in this 11 instance, and you have a list of risks under adverse 12 reactions. 13 Do you see that? 14 A. Yes. 15 Q. And it starts with hematoma and goes through 16 procedure failure. 17 A. Yes. 18 MS. SUTHERLAND: Can we go off for a minute? 19 (Recess.) 20 BY MS. SUTHERLAND: 21 Q. We were looking at the risks you have listed 22 under adverse reactions from hematoma to procedure 23 failure; correct? 24 A. Yes. 25 Q. Now, you understand that there are ways, other</p>	<p>1 first grouping, from hematoma to procedure failure, are 2 there risks there that you don't have if you don't use 3 mesh? And you told me contracture, which you equated to 4 contracture of mesh; correct? 5 A. Yes. I would also add, although pain is listed 6 here -- you have to define what the list is, and it's 7 defined in my report that these were, this particular 8 list, is a list of adverse events that Ethicon had been 9 requested, in this case by FDA, to add to the Prolift. 10 Q. That's not what I asked you. I didn't ask you 11 anything about that. 12 A. We're talking about a specific list. 13 Q. There's no question pending. 14 A. I'm still answering the prior question. You 15 asked me if these were all -- if that was the only one. 16 Pain is listed here because that's how it was 17 presented by FDA, but chronic pain is not listed here, 18 and chronic pain is something, for example, that you find 19 with mesh and typically not with other procedures. 20 Q. Do you have chronic pain at all with other 21 procedures to fix prolapse when you don't use mesh? 22 MR. KUNTZ: Objection. 23 BY MS. SUTHERLAND: 24 Q. Have you seen that in the literature? 25 A. Not in the same fashion.</p>

24 (Pages 90 to 93)

Peggy Pence, Ph.D.

<p style="text-align: right;">Page 94</p> <p>1 Q. Have you seen it in the literature?</p> <p>2 A. To the best of my recollection, it may be a</p> <p>3 possibility, but not to the extent or the severity or the</p> <p>4 life-altering way that you see with mesh.</p> <p>5 Q. The question to wrap up -- assuming, when we</p> <p>6 come back March 24th, I think I can figure the rest of</p> <p>7 this out through the TVT aspect.</p> <p>8 My question to wrap up here before I race to my</p> <p>9 car is, is there a standard that you're relying on that</p> <p>10 tells a manufacturer the risks that the manufacturer has</p> <p>11 to warn about associated with the device versus</p> <p>12 associated just with a procedure --</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 THE WITNESS: I just --</p> <p>15 BY MS. SUTHERLAND:</p> <p>16 Q. -- other than the blue book memo?</p> <p>17 A. I just read a few moments ago.</p> <p>18 Q. Is it the ones you already stated?</p> <p>19 A. Yes. Stating as well that based on my review</p> <p>20 of various documents, that for mesh, separating out the</p> <p>21 procedure from the device, and, in fact, talking about</p> <p>22 the procedure, FDA just had in February a panel meeting</p> <p>23 on reclassification of the instrumentation.</p> <p>24 Q. I didn't ask you anything about</p> <p>25 reclassification.</p>	<p style="text-align: right;">Page 96</p> <p>1 EXAMINATION</p> <p>2 BY MR. KUNTZ:</p> <p>3 Q. I got one question real quick.</p> <p>4 Dr. Pence, you have also reviewed numerous</p> <p>5 depositions from Ethicon internal employees, including</p> <p>6 Medical Directors Weisberg, Dr. Robinson, Pete Haniel,</p> <p>7 and regulatory professionals, like Kathryn Breach;</p> <p>8 correct?</p> <p>9 A. That's correct.</p> <p>10 Q. Do they set forth in their testimony what they</p> <p>11 believe Ethicon or a manufacturer has to set forth in</p> <p>12 labeling?</p> <p>13 A. Yes, they do.</p> <p>14 Q. And to the best of your recollection, what do</p> <p>15 those individuals say needs to be put in IFUs in labeling</p> <p>16 with respect to adverse events?</p> <p>17 A. Adverse reactions that are known, and there's</p> <p>18 testimony that says all of these adverse reactions were</p> <p>19 known from the start of the implementation of these</p> <p>20 products, as well as warnings and contraindications.</p> <p>21 MR. KUNTZ: No more questions.</p> <p>22 MS. SUTHERLAND: To be continued.</p> <p>23 (Time noted: 11:45 a.m.)</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 95</p> <p>1 A. That has to do with the procedure.</p> <p>2 Q. The question is just on the standards.</p> <p>3 A. Separating out the procedure and the device for</p> <p>4 these mesh products, I don't believe it's my opinion you</p> <p>5 can do that, and that all the hazards and any expected</p> <p>6 and foreseeable side effects should be included and any</p> <p>7 residual risk identified according to the standards as I</p> <p>8 discussed them.</p> <p>9 Q. This really is the last question.</p> <p>10 Is there a manufacturer that has met that</p> <p>11 standard in the pelvic mesh arena?</p> <p>12 A. Because I haven't reviewed the information for</p> <p>13 every manufacturer, that type of information for every</p> <p>14 manufacturer in the mesh arena, I'm unable to answer that</p> <p>15 question.</p> <p>16 Q. For the ones you have reviewed, how many have</p> <p>17 you reviewed?</p> <p>18 A. Boston Scientific, Bard, and Ethicon, and</p> <p>19 certain products, not all products for every one of them.</p> <p>20 Q. For the ones you have reviewed, none of them</p> <p>21 have met the standard you just set out?</p> <p>22 A. That's correct.</p> <p>23 MS. SUTHERLAND: That's it.</p> <p>24 ///</p> <p>25 ///</p>	<p style="text-align: right;">Page 97</p> <p>1 DECLARATION UNDER PENALTY OF PERJURY</p> <p>2 Case Name: AMSDEN VS. ETHICON</p> <p>3 Date of Examination: March 9, 2016</p> <p>4 Job No.: 125666</p> <p>5 I, PEGGY PENCE, PH.D., hereby certify</p> <p>6 under penalty of perjury under the laws of the State of</p> <p>7 _____ that the foregoing is true and correct.</p> <p>8 Executed this _____ day of _____,</p> <p>9 20____, at _____.</p> <p>10</p> <p>11 _____</p> <p>12 PEGGY PENCE, PH.D.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

25 (Pages 94 to 97)

Peggy Pence, Ph.D.

<p style="text-align: right;">Page 98</p> <p>1 I, KRISTI JOHNSON, CSR No. 12585, Certified</p> <p>2 Shorthand Reporter, certify;</p> <p>3 That the foregoing proceedings were taken</p> <p>4 before me at the time and place therein set forth, at</p> <p>5 which time the witness declared under penalty of perjury;</p> <p>6 that the testimony of the witness and all objections made</p> <p>7 at the time of the examination were recorded</p> <p>8 stenographically by me and were thereafter transcribed</p> <p>9 under my direction and supervision;</p> <p>10 That the foregoing is a full, true, and correct</p> <p>11 transcript of my shorthand notes so taken and of the</p> <p>12 testimony so given;</p> <p>13 () Reading and signing was requested.</p> <p>14 () Reading and signing was waived.</p> <p>15 (X) Reading and signing was not requested.</p> <p>16 I further certify that I am not financially</p> <p>17 interested in the action, and I am not a relative or</p> <p>18 employee of any attorney of the parties, nor of any of</p> <p>19 the parties.</p> <p>20 I declare under penalty of perjury under the</p> <p>21 laws of California that the foregoing is true and</p> <p>22 correct.</p> <p>23 Dated this 14th day of March, 2016.</p> <p>24</p> <p>25 _____</p> <p style="text-align: center;">KRISTI JOHNSON, CSR No. 12585</p>	<p style="text-align: right;">Page 100</p> <p>1 EXAMINATION ERRATA SHEET</p> <p>2 Page _____ Line _____ Reason _____</p> <p>3 From _____ to _____</p> <p>4 Page _____ Line _____ Reason _____</p> <p>5 From _____ to _____</p> <p>6 Page _____ Line _____ Reason _____</p> <p>7 From _____ to _____</p> <p>8 Page _____ Line _____ Reason _____</p> <p>9 From _____ to _____</p> <p>10 Page _____ Line _____ Reason _____</p> <p>11 From _____ to _____</p> <p>12 Page _____ Line _____ Reason _____</p> <p>13 From _____ to _____</p> <p>14 Page _____ Line _____ Reason _____</p> <p>15 From _____ to _____</p> <p>16 Page _____ Line _____ Reason _____</p> <p>17 From _____ to _____</p> <p>18</p> <p>19 _____ Subject to the above changes, I certify that the</p> <p>20 transcript is true and correct</p> <p>21 _____ No changes have been made. I certify that the</p> <p>22 transcript is true and correct.</p> <p>23</p> <p>24 _____</p> <p>25 PEGGY PENCE, PH.D.</p>
<p style="text-align: right;">Page 99</p> <p>1 EXAMINATION ERRATA SHEET</p> <p>2 Case Name: AMSDEN VS. ETHICON</p> <p>3 Name of Witness: PEGGY PENCE, PH.D.</p> <p>4 Date of Examination: March 9, 2016</p> <p>5 Job No.: 125666</p> <p>6 Reason Codes: 1. To clarify the record.</p> <p>7 2. To conform to the facts.</p> <p>8 3. To correct transcription errors.</p> <p>9</p> <p>10 Page _____ Line _____ Reason _____</p> <p>11 From _____ to _____</p> <p>12 Page _____ Line _____ Reason _____</p> <p>13 From _____ to _____</p> <p>14 Page _____ Line _____ Reason _____</p> <p>15 From _____ to _____</p> <p>16 Page _____ Line _____ Reason _____</p> <p>17 From _____ to _____</p> <p>18 Page _____ Line _____ Reason _____</p> <p>19 From _____ to _____</p> <p>20 Page _____ Line _____ Reason _____</p> <p>21 From _____ to _____</p> <p>22 Page _____ Line _____ Reason _____</p> <p>23 From _____ to _____</p> <p>24 Page _____ Line _____ Reason _____</p> <p>25 From _____ to _____</p>	

26 (Pages 98 to 100)

Peggy Pence, Ph.D.

Page 101

A				
abandoned 69:1 abbrevo 39:8 able 33:24 34:2 64:13 79:8 absolutely 26:24 acceptable 70:7 accepted 69:9,14 71:1,5,18 72:25 74:14 account 64:19 accurate 47:10 52:25 action 1:9,11,12,14 1:16,18,20,22,24 2:2,4,6,7,9,11,13 2:15,17,19,21,23 3:2,4,6,8,10,12,14 3:16,18,20,22,24 4:2,4,6,8,10,12,14 4:16,18,20,22,24 5:2,4,6,8,10,12,14 5:16,18,20,22,24 6:2,4,6,8,10,11,13 6:15,17,19,21,23 98:17 actions 32:16 actual 17:21 40:13 47:23 add 25:18,21 26:3 27:23 32:7 53:1 93:5,9 added 25:13,24 26:1 28:16,21 32:9,11 53:6,7 adding 53:3 addition 87:9 additional 18:22 25:18 29:17 37:5 54:6 57:11 80:5 additionally 23:24 25:8 89:5 additions 32:3,4,7 address 10:14,17 10:18,25 16:6,9 51:22 52:21,21,25	55:9 67:19 83:20 addressed 12:18 addressing 26:17 26:25 27:4 48:11 adequate 77:23 84:20 adequately 79:4 81:12 adopting 37:17 advamed 33:10,22 33:25 34:19,20,21 34:23 35:1,6,9,16 35:20,21,22,24 36:2 adverse 41:13,19 41:24 42:3 48:24 91:11,22 93:8 96:16,17,18 advisory 34:24 affairs 54:25 agencies 33:3 ago 12:20,22,25 27:2 28:23 94:17 agree 22:4 90:25 agreed 52:4 65:1 agreement 65:10 ahead 53:21 64:7 aim 33:19 37:3 al 1:13,14,18,20,21 1:22,23,24 2:1,1,3 2:3,5,9,10,11,12 2:14,15,17,18,19 2:20,21,23,24,25 3:1,3,3,5,5,7,9,11 3:13,15,15,17,17 3:19,21,21,23,23 4:1,3,3,5,7,9,9,11 4:11,13,15,17,17 4:19,19,21,21,23 5:1,3,3,5,7,9,9,11 5:13,15,17,17,19 5:19,21,23,23 6:1 6:1,3,3,5,7,9,13 6:15,18,19,21,23 alert 45:10 alfreda 4:11	allow 23:11 27:1 allowed 28:10,10 29:20 40:9 allows 22:1 76:3 83:7 alternative 82:7 amanda 2:10 amgen 39:24 amount 12:17 65:23 ams 45:25 amsden 1:9 97:2 99:2 ana 5:13 analogous 12:10 analyses 13:22 analysis 39:25 46:12 47:13,24,25 48:14,15 74:19 75:6 82:1 90:22 analyst 39:17,17,24 analytics 39:25 analyze 75:17 77:6 analyzing 75:20 angela 2:3 annual 54:25 answer 12:24 24:1 30:12 62:20 76:20 84:19,20 95:14 answered 76:18 78:19 79:11 82:10 82:23 83:10,25 92:25 answering 93:14 answers 62:22 anticipate 22:18 44:5 48:8 anticipating 47:24 apologize 56:1 apparently 56:5 appear 20:16 48:7 48:8,19 appearances 7:9 appeared 44:5 appears 16:21 20:23 27:18 35:23	43:14 55:6 applicable 31:17,21 31:24 70:1 applied 39:9 applies 24:9 appreciate 18:25 approach 29:4 48:17 appropriate 28:14 47:8,10 48:12 85:2 appropriately 90:19 approximately 60:9,14 april 11:6 14:14 archived 37:24 archives 37:19 arena 95:11,14 arent 30:14 53:14 61:20 arm 80:23 article 18:6 64:13 64:14 articles 18:6 57:21 57:22 aside 51:20 asked 12:22 36:6 48:2 49:11 54:23 56:4,7 57:5 61:10 61:17 62:6 70:25 78:19 84:3,4 85:9 85:10,11 93:10,15 asking 15:4 46:19 49:21 61:8 74:12 aspect 94:7 assess 79:4 81:12 assessment 14:6 71:10 73:23 89:7 assignment 13:16 associated 70:7 89:23 91:1,2 94:11,12 assume 11:16 assuming 55:22 94:5	assurance 11:10 attach 51:12 attached 21:15 23:19 24:3 59:12 attachment 25:7 attempt 48:22 attended 53:5,13 attention 43:23 attorney 47:20,21 98:18 attorneys 47:14 authored 79:23 authoritative 25:20 25:22 81:13 82:13 82:20 83:6,13 authorization 83:2 83:6,14 authors 62:21 available 22:7,16 23:16 24:4 29:5 33:16 34:17 35:25 43:1,4 45:15,17 48:1 57:7 76:6,10 76:14 78:1,11 79:9 82:7 90:16 avenue 7:13 aware 45:12
				B
				b 68:17 88:24 bachelors 39:23 40:4 back 11:24 12:5,19 12:20 14:2 15:18 15:24 16:5,6,9 17:4 18:3 25:11 28:4,22 30:19,21 44:4 46:5 47:22 50:5 52:9 54:15 56:19 57:15,18 67:22 69:8 70:20 70:22,25 71:15 72:5 73:25 74:2 85:18 87:22 94:6 background 39:15 39:16,20

ballpark 60:20 banks 1:10 barbara 3:21 4:5 bard 95:18 base 29:22 based 28:9 35:23 37:23 47:14 74:12 76:2,10,13,16 78:2 80:4,15,21 83:12 85:3 94:19 basically 52:24 basis 77:20 78:9,22 batch 61:4,8 bayview 7:5 beach 1:12 7:6 10:1 10:15 16:10 began 11:25 begins 27:16 behalf 7:3 believe 19:7 20:13 29:6 33:25 34:1 39:21,22 40:4 56:14 82:21 95:4 96:11 benefit 72:7 benefitrisk 69:11 71:10,22 74:19 75:6,18 76:15 77:24 78:2,5,18 79:9 81:12 82:2,6 benefitriskratio 79:5 benefits 70:8 benefitorisk 75:20 76:25 77:6 best 12:7 19:2,11 30:12 33:24 34:1 34:2 39:21 43:22 60:15,24 62:6 63:11,14,23 65:7 74:6 87:19,20 94:2 96:14 beth 2:1 better 35:13 betty 3:1 beyond 82:15	bias 64:15 billed 60:1 binder 8:18,20,22 8:23 15:2 16:18 17:10 18:4,5,7,14 19:22 20:4,9 37:22 38:4 87:16 87:24 binders 15:14 16:13 biology 11:10 biotechnology 11:13 bit 47:4 bjog 65:1,16,23 66:9,12 blue 18:5,13 89:20 94:16 bodies 25:20,22 81:13 82:13,20 body 15:12 41:18 83:1,6,13 boggs 1:13 bollinger 1:15 book 89:20 94:16 boston 9:6 27:4 28:5 33:25 36:11 36:13 43:7 48:19 56:5 95:18 bottom 71:2 90:5 brain 41:10 brandnew 76:12 breach 96:7 breached 62:18,25 break 52:11 bridges 1:17 brightline 77:4 78:6,15 79:1,7,8 bring 14:24 broader 29:22 broken 42:10 brought 15:1,6 19:21 bsc 55:24 buckets 67:20 burkhart 1:19	burned 41:10 business 10:17 busy 14:15 butler 7:17 butlersnow 7:20 byrd 1:21 <hr/> C <hr/> calculation 49:14 california 7:6 10:1 10:15 11:13 16:10 98:21 call 43:8,20,24,25 47:2 called 10:5 16:19 19:15 calling 46:25 47:12 cambridge 68:24 campus 11:15 canada 25:14,15 cant 11:25 33:13 34:18 40:22 42:7 56:21 57:15 77:8 78:4 85:4 caps 31:11 car 94:9 care 69:10,15 71:2 71:5,18 74:14 carey 2:1 62:10 65:5,24 68:23 careys 64:2 65:2 carpenter 1:23 carrie 5:21 cartmell 7:12 case 15:3 74:5 78:22,22 89:14 93:9 97:2 99:2 casebycase 78:9 80:20,24 cases 1:7 cathy 6:14 caught 58:20 59:10 causes 48:23 caveat 21:19 cavness 17:6,7,8 62:7 67:22	certain 13:10 29:20 50:16 56:17 62:12 66:20 83:12 95:19 certainly 34:19,23 35:5 40:24 48:1 74:4 certified 98:1 certify 97:5 98:2,16 100:19,21 cfr 63:4 chair 54:24 challenges 61:23 68:18 chance 65:7 change 23:21 changed 23:7 56:2 69:1 changes 22:11 100:19,21 channel 11:14 characteristics 61:12 charlene 4:23 charleston 1:3 chart 42:1 44:7,24 44:25 charter 68:11,15,20 69:6 charts 38:14 check 13:4 14:2 19:6,7,13,15 21:1 21:3 43:17 48:6 63:24 82:22 87:25 checking 11:24 12:5,19 21:14 44:4 46:4 cherise 6:1 chose 56:21 christine 6:18 17:23 38:20 39:14 43:23,25 48:22 51:9 60:14 chronic 93:17,18 93:20 circle 7:5 cite 24:5 63:15	city 7:14 civil 1:9,11,12,14 1:16,18,20,22,24 2:2,4,6,7,9,11,13 2:15,17,19,21,23 3:2,4,6,8,10,12,14 3:16,18,20,22,24 4:2,4,6,8,10,12,14 4:16,18,20,22,24 5:2,4,6,8,10,12,14 5:16,18,20,22,24 6:2,4,6,8,10,11,13 6:15,17,19,21,23 clarification 74:20 clarify 32:25 47:1 58:9 61:3 99:4 clark 10:13 class 11:6,16 13:2 13:10,12,17 14:1 14:3,13 75:21,23 75:24 clear 57:5 67:20 cleared 66:20 clearly 57:19 clinical 9:9 11:10 14:5,10 19:5,6,23 20:13 55:16 57:2 62:10,13,14 65:9 67:1,5 68:22 69:10,11 70:5 71:19,19,20,21 72:8,10 73:3,9,17 73:21 74:15,15,16 74:18 75:5,9,10 75:14,17 76:8,15 76:19,24 77:5,9 77:10,14,16,17 78:3,4,7,17 79:3 79:14,19,20,21,22 80:2,6,16,18 81:11 83:21 84:18 84:24 90:16 clinically 90:18 close 35:7 codes 99:4 cole 2:1
--	---	---	--	--

Peggy Pence, Ph.D.

Page 103

coleman 2:3 college 40:3 collins 2:5 colony 7:18 colored 16:22 column 40:18 44:8 columns 38:23 44:6 48:7,9,20 49:25 com 7:15,20 combination 90:10 combined 39:7 40:19 42:12 come 38:22 41:17 70:11,22 71:15 85:2 94:6 comes 14:8 70:12 coming 51:22 75:12 commencing 7:4 commercial 75:10 76:4 77:22 commitment 83:5 83:11 communication 50:25 companies 33:19 company 76:23 77:15 82:9 comparing 76:10 comparison 32:10 57:12,21 80:19 compatible 70:9 competitor 76:7 compilation 15:8 complete 76:21,22 82:11 completely 46:15 comprehensive 29:4,21 88:14 compromise 70:5 concerns 28:9 65:4 conclusions 13:22 concomitant 48:23 condition 70:5 conditions 69:25 70:3 conducted 67:22	83:22 cone 2:7 conference 12:9,11 conferences 53:4 53:13,14 confess 62:8 confirm 33:24 conflict 66:10 conform 99:4 conformance 89:13 conformity 14:6 73:19,23 89:7,12 confusing 74:9 confusion 16:5 consensus 32:16 consider 92:18 consideration 57:4 64:14 considered 37:23 37:25 38:2,8 56:25 considering 77:24 consistent 50:22 90:16 constitute 70:7 consulting 66:1 consumer 33:7 contain 86:1 contained 25:12 71:6,8,24 87:12 containing 8:22,23 contents 88:23 context 81:21 conti 2:8 continue 83:11 continued 9:1 96:22 continuing 53:5 54:22 contract 14:17 contracture 92:12 93:3,4 contraindications 90:14,23 96:20 controlled 55:15 56:22 57:2,6,19	convoluted 35:12 coordinated 18:2 copies 15:14 17:15 20:4,7 copy 19:21 22:19 22:21,23 41:9 55:3,5 corporation 9:6 correct 21:13,14 24:13 26:8,14 29:9,10,13 30:22 31:2,9,17 32:2,22 37:13 42:10,13 44:14 53:2 55:13 61:1,25 64:21,22 66:5 69:13 72:1 75:22 77:2 86:4,5 89:24 91:23 92:1 92:1 93:4 95:22 96:8,9 97:7 98:10 98:22 99:5 100:20 100:22 corrected 55:18 correctly 11:11 26:1 27:23 28:5 29:6 41:8,12 46:16 47:18 51:11 55:2,24 62:16 65:18 67:13 74:9 83:16 counsel 7:9 59:15 county 54:25 couple 14:18 28:22 51:22 53:1 58:11 60:17 course 11:12,14,23 12:1 13:7 23:18 23:20 25:17 26:5 56:22 57:3 75:24 court 1:1 14:22 16:24 17:18 18:9 18:16 20:20 21:9 27:12 51:15 70:17 72:16 86:17 courts 29:20 cover 12:16,17	67:14 covers 52:2 created 68:3 creating 73:16 cross 19:11 csr 7:4 98:1,25 curious 36:19 current 19:8 20:14 37:23 38:1,2,6,8 87:23 currently 11:5 85:14 cut 66:17 cv 52:18 53:14 54:17,18 55:8 59:3 cynthia 5:1	decided 25:18 decision 80:18,20 80:24 decisions 32:16 declaration 97:1 declare 98:20 declared 98:5 dee 4:21 defect 61:2 defendant 7:16 defendants 7:3 14:21 16:23 17:17 18:8,15 20:19 21:8 27:11 51:14 70:16 72:15 86:16 defense 58:7,11,14 define 48:14,15 93:6 defined 90:9 93:7 definitely 43:16 52:3 65:12 degree 39:23 40:3 deleon 2:10 delineate 17:16 delineated 17:11 45:21 demonstrate 71:21 73:18 78:5 79:9 84:13,21 85:3 demonstrating 89:12 denise 1:19 2:5 denominator 49:7 denoted 56:18 dependent 81:7 83:8 depending 56:24 78:9 depends 81:1 82:6 82:7 depo 14:20 16:3 51:21,24 deposed 22:12 42:8 deposition 1:13 7:2 7:6 8:11 20:18 21:7 23:14,19
--	--	--	---	---

24:2,3 25:6 27:21 58:24 60:19 71:6 depositions 96:5 described 49:3 88:20 description 41:19 designed 69:24 designing 80:16,18 85:1 destefanoraston 2:12 detail 51:2 determination 76:23 determines 80:22 determining 48:22 developed 32:12 developing 65:9 development 61:22 64:23 66:3 68:18 68:24 73:1,17 device 13:13,18 31:13 53:11 61:2 61:7 69:10 71:10 71:19,22 74:15 75:12,15 76:11,13 76:17 77:11,15,19 77:20,24,25 78:8 78:10,12,12,13 81:1 88:6 89:24 91:2 94:11,21 95:3 devices 9:8,11 12:12,12,13 24:15 46:23 47:17 69:9 69:24 70:14 71:17 71:25 73:1,7,24 74:11,13,18,23 75:5,21,23,24 76:1,1,3,4,11,17 77:4,21,25 78:11 81:20 85:25 87:14 88:23 89:4,7,9,13 89:15 diagnostic 74:11 didnt 23:21 47:2	49:1 53:23 54:5,7 55:18 56:1 61:18 63:15 87:4,21 88:2 93:10 94:24 difference 92:20 differences 74:7,10 77:25 78:10 different 32:1 36:22 38:14,23 46:13 55:17 79:7 80:19 91:8 dina 2:12 directed 34:10 direction 38:20 41:7,15 98:9 directors 96:6 disband 37:7,14 disbanded 37:1,9 disclose 63:1,21 disclosed 63:4 disclosure 62:12,18 63:3,12,25 64:1 64:11,18 65:14,22 66:6,11 disclosures 63:5 discussed 95:8 discussing 72:20 discussion 41:18 51:8 55:1 65:19 90:6 distinctions 76:16 district 1:1,2,6 dividing 67:7 division 1:3 document 1:7 15:8 25:17 31:4 45:16 56:5 63:20 66:10 69:4 70:12,19 72:23 73:4,5,8,10 73:11,12 79:22 80:9 86:4,9,14,23 86:24 87:8,10 88:19 89:6,15 documentation 8:20 83:16 89:11 documents 8:22,24	14:24 15:4,8,10 15:11 17:21,25 18:11,14,19 30:16 32:12 37:20,21,21 37:24 38:2 59:22 63:17,18 69:16 72:4,24 73:13,15 73:22 78:6,16 79:2 80:11 86:19 87:6,17,23,24,24 88:6,8,9,10,15,16 88:21,25 89:3,8 89:17,18 90:2 94:20 doesnt 19:21 20:15 47:6,7 77:10 doing 11:25 12:14 25:17 28:12 34:10 41:7 48:13 51:24 57:12 80:6,19 81:2,4 85:1 donna 1:9 3:15 4:17 dont 12:5,18 20:13 22:3,20,25 23:3,9 27:6 33:16 34:14 34:22 35:25 36:4 36:9,9,15,18 37:8 39:21,22 40:4,9 41:9 42:10 45:15 45:24 46:4,24,24 47:21 48:10 49:16 49:17 57:5,17 58:4,10 59:1,14 64:7 66:13 75:13 75:13 77:3 81:3 82:4 85:11 92:8 92:11,11,14 93:2 93:2,21 95:4 double 19:5,15 43:17 63:24 82:22 87:25 dr 8:12 10:14 21:16 22:10 23:14,18 24:2 25:6 27:21 54:2,17 64:2 65:1	65:3,5,24 68:23 68:24 77:2 96:4,6 draft 24:23 25:4 65:5 drafted 26:17 31:5 85:5 drake 2:14 drive 10:15 16:10 drop 81:2 drug 13:13,18 drugs 12:10,13 duly 10:5 duplicate 43:8,16 43:24 duplicates 43:20 dyspareunia 41:24 50:19 <hr/> E <hr/> e 2:14 8:1 earlier 36:21 88:20 early 25:2 ease 27:16 easily 21:4 education 53:5 54:22 70:2 educational 39:20 effectiveness 85:3 effects 90:20 95:6 efficacy 67:6,15,17 84:14 effort 15:23 efforts 43:8,20,25 73:18 either 15:25 49:1 54:9 77:22 emphasis 90:17 employee 98:18 employees 10:24 96:5 employer 40:10 enrolled 84:7 equal 33:19 36:25 37:3 equated 93:3 erosion 41:23 50:1	erosions 50:17 errata 99:1 100:1 errors 99:5 esq 7:12,17 essential 9:7 14:4 69:18,20,22 70:13 71:24 72:5 73:2,6 73:8,10,19,25 74:2 88:22 89:2 89:12 essentially 12:16 34:9 39:3 80:20 establishing 29:3 estimate 60:24 et 1:13,14,18,20,21 1:22,23,24 2:1,1,3 2:3,5,9,10,11,12 2:14,15,17,18,19 2:20,21,23,24,25 3:1,3,3,5,5,7,9,11 3:13,15,15,17,17 3:19,21,21,23,23 4:1,3,3,5,7,9,9,11 4:11,13,15,17,17 4:19,19,21,21,23 5:1,3,3,5,7,9,9,11 5:13,15,17,17,19 5:19,21,23,23 6:1 6:1,3,3,5,7,9,13 6:15,18,19,21,23 ethicon 1:5,9,10,12 1:14,15,17,19,21 1:24 2:1,3,5,7,8 2:11,13,15,16,19 2:20,22,25 3:1,3,5 3:7,9,11,13,15,17 3:19,21,23 4:1,3,5 4:7,9,11,13,15,17 4:19,21,23 5:1,3,5 5:7,9,11,13,15,17 5:19,21,23 6:1,3,5 6:7,9,11,12,14,16 6:19,20,22 8:14 15:10,11 23:7 24:15 25:13 27:24 34:12,14,25 35:9
---	--	---	---	---

Peggy Pence, Ph.D.

Page 105

35:15,20 39:6 40:18,25 42:12 44:8 46:1,23 48:4 48:4,18 49:25 60:5 61:2,7 62:17 62:21,25 64:22 65:12 68:2,4,9,22 93:8 95:18 96:5 96:11 97:2 99:2 ethicons 65:6 66:7 evaluate 57:1 76:3 78:18,21,21 evaluated 51:5 evaluation 9:9 14:6 62:10 68:23 69:10 71:19 72:8,10 73:3,10,21 74:15 event 41:19,24 42:11 44:20,22 events 41:14,19 42:3 48:24 50:1,7 50:11 93:8 96:16 evidence 19:5 20:13 29:5 56:24 56:25 57:20 78:2 79:10 exact 22:20 39:8 exactly 11:25 29:17 43:17 52:23 56:21 examination 8:3 10:8 96:1 97:3 98:7 99:1,3 100:1 examined 10:6 example 13:14 33:10,25 38:25 39:6,23 41:8 43:7 45:24 47:24 50:23 51:5 54:20,24 69:19 71:14 72:7 72:23 73:1 79:25 80:10 81:4,5 82:21 88:21 93:18 exclude 29:3 excluding 28:18 65:19,21 executed 97:8	exhibit 8:11,12,14 8:16,18,20,22,23 9:5,7,9,10 14:21 16:18,23 17:9,17 18:8,13,15 19:17 19:18,24 20:2,4 20:18,19 21:7,8 27:11,22 28:3,20 31:16,21,24 32:1 32:14 37:22 38:9 42:9,24 43:12,12 43:21 46:17 50:10 51:14 52:17 53:17 54:18 55:12,20 56:1 57:8 69:17 69:19 70:15,16 71:6 72:15 73:4,7 73:22 79:21 81:19 81:21 86:16 88:21 89:1,5,11 90:5 exhibits 8:9 9:3 16:14 17:1 20:25 21:5,15 23:19 24:3 25:7 30:22 31:2 58:21 59:13 existence 73:14 exists 71:22 expect 63:2 expected 90:19 95:5 experience 31:14 39:25 70:2 71:21 75:10,14 76:4,8 77:22 expert 8:12,14,18 8:21 16:20 20:23 21:21 29:14,18 58:7,11,14 extensive 39:25 extent 12:15,18 38:16 65:13 88:4 94:3 extract 39:10 41:23 eye 81:2	f 2:7 facility 31:13 fact 23:6 25:12 30:8 43:20 47:21 50:25 59:4 64:24 92:17 94:21 factory 61:15 facts 99:4 failed 68:2 failure 25:19 62:25 91:16,23 92:7 93:1 failures 61:23 68:18 fair 13:5 28:16 66:21 familiar 17:6 92:5 family 49:8 far 24:15 38:13 60:5 fashion 93:25 favorable 68:25 69:11 71:9,21 72:7 76:14,25 77:23 78:2,5 79:9 82:6 fda 8:22 11:17 15:6 18:11 28:8,9,13 28:19,24 29:12,19 30:3,9,12,15 35:2 35:10,17 37:12 38:15 39:11 45:11 49:4 51:4,5 54:25 63:4,5,9 64:6,8,9 65:19,20,21,21 66:19,19 82:16,19 83:3,4 93:9,17 94:22 fdas 50:22 february 8:18 16:19 20:24 22:8 22:17,24 23:16 24:5,10 25:2 28:2 28:17 31:16,21,25 32:6 52:9,18 59:5 60:12 79:24 87:16	94:22 feel 25:21 felt 25:5 32:8 figure 94:6 file 23:11 52:5 filing 21:20 final 8:24 18:14 70:12 87:17 financial 62:12,18 63:1,3,4,12,21 64:4,16 65:14,25 66:6 financially 98:16 find 27:17 34:2,4,5 34:9,11 36:23 66:5 93:18 fine 64:11 first 10:5 25:12 26:2 28:3 31:21 33:21 41:6 44:18 66:15 67:25 69:22 83:20 85:20,22,23 87:18 92:7 93:1 fisk 2:16 five 16:22 20:25 21:5 23:5 32:19 32:20 34:13 37:4 49:21 55:24 59:13 61:24 82:14,15,17 82:18,24 fix 93:21 flap 18:6 flip 61:21 focus 64:9 focuses 66:18 focusing 31:1 67:22 75:1 follow 30:7 40:2 55:7 65:5 68:2 81:3,5 followed 68:4 following 1:7 83:12 91:3 follows 10:6 followup 19:6,24 82:1	footnote 17:12 20:1 20:2 69:2,4 86:3 86:20 footnoted 15:9 18:21 54:4,9 footnotes 15:12 18:1 19:14 force 9:7,9,10 11:20 70:13 79:24 foregoing 97:7 98:3 98:10,21 foreseeable 90:19 95:6 forester 2:18 forgotten 53:7 form 71:20 74:16 75:9 77:7 forth 96:10,11 98:4 found 50:23 51:3,4 57:22 foundation 79:18 founding 37:4 four 23:5,8 24:12 24:19 58:22 fox 2:20 frame 32:6,21 33:15 35:17 83:18 fran 2:5 frankly 22:1 free 2:22 8:16 freeman 2:24 frequency 92:21 front 18:6 full 10:12 85:18 98:10 funderburke 3:1 further 23:4 32:11 98:16
G				
general 81:24 generally 56:24 63:2 64:21 generation 81:10 georgilakis 3:3 getting 59:1				

ghtf 8:24 11:22 12:2,10,12 13:3,7 13:14,25 15:4 18:14,18 20:5 26:5,6,9,12 27:24 28:3,4,6,8,15,17 28:22 30:13,16,16 32:12,15,20 33:2 33:11 34:13,21 35:4,11,21 36:3,8 36:14,25 37:7,14 37:17,19,20,21 38:2 63:13,17,20 71:11,24 72:3,24 73:14 75:16 77:2 78:6,15 79:1,19 80:8 86:3,23 87:5 87:17,24 90:2 give 13:9,12,19,23 16:8 40:22 41:7 41:15 49:18 63:5 67:10 77:8 79:25 83:1 84:13 85:4 given 23:5 49:12 98:12 gives 80:4,5,6 global 9:7,9,10 11:19 70:12 72:25 73:16 79:23 globally 85:24 86:10 go 18:24 19:12 37:18,23 41:22 50:5 52:9,14 53:21 64:7 66:23 69:8,18 72:7 74:2 79:12,17 80:25 81:11 85:18 86:1 91:18 goes 11:8 32:1 44:23 66:10 76:5 91:15 going 14:13,19 20:17 21:6,19 22:2 27:9,17 52:12 61:14,15	64:2 66:16 70:15 72:13 80:22 83:1 83:8 86:14 87:2 92:15,17 golkow 15:21 gomez 3:5 good 10:10,11 21:22 goodness 85:12 goodwin 1:5 9:5 26:16,25 27:15 goodwins 28:18 88:5,12 grabowski 3:7 graduate 40:5 graduatelevel 11:12 grand 7:13 graywheeler 3:9 great 36:23 39:16 group 34:23 35:10 36:16 55:1 79:23 grouping 93:1 groups 32:19,20,24 33:11,18,20,22 34:7,13 35:11 36:22 37:5 guess 49:10 guest 14:7 guidance 8:24 18:14,19 30:16 72:3 89:6 guidances 11:20,23 13:8,9,12,14,19 13:21,25 14:6,7,9 20:7,8 30:13 37:17 guiding 20:5 guinn 3:11 guys 49:12 gynemesh 22:11	hand 14:19 17:3 18:3 20:17 21:6 27:9 51:12 70:15 86:14 handed 86:22 handing 72:18 86:19 hankins 3:13,15 hanuel 96:6 happen 14:18 45:9 88:3 happens 73:7 happy 65:11 harmonization 9:7 9:9,10 11:20 12:9 12:11 70:13 79:24 harmonize 30:17 harriet 1:12 havent 30:25 60:22 85:5 95:12 hazards 90:17,17 95:5 headtohead 57:12 health 8:15 25:14 25:14 50:24 70:9 hear 43:15 heart 85:13 heather 4:15 heavily 64:23 help 46:22 52:1 helped 56:3 helpful 26:3 32:8 hematoma 91:15 91:22 92:7 93:1 hendrix 3:17 herreranevarez 3:19 high 40:5 57:20 70:9 75:25 highest 56:23,25 highland 7:18 hill 3:21 history 37:2 holly 4:3 home 10:18 homes 11:2	hon 1:5 hooper 3:23 hour 52:12 59:20 hourly 59:18 hours 60:1,9,14,15 60:15,23 human 75:5 humans 77:5,16,18 78:17 79:3 hundred 40:23,24 hurts 21:3 hypothetical 49:11	65:18 66:16,25 67:7,13,22 68:16 68:16 69:8 70:15 70:25 72:18,24 74:9,12 75:1,3 77:13,14 80:1 85:18 86:14 87:2 87:22 88:8 91:9 92:15 93:14 95:14 imdrf 37:1,10,11 37:12,16,18,20,24 38:6,8 implant 81:4,8,25 82:3 implantable 81:20 implanted 44:2 48:3,18 53:11 implants 81:15 implementation 19:20 96:19 important 25:17,24 57:4 importantly 68:14 68:19 90:9 impossibility 49:13 impossible 49:18 improper 49:11 inadequate 67:1 inappropriate 47:3 48:10 include 11:17,19 13:14 14:9 19:19 20:4,6 28:14 29:23 33:5 47:2,3 47:8,19 48:10,13 55:25 59:14 72:6 77:10 87:23 88:3 90:8,13 included 20:16 25:10 26:7,9 28:4 28:6,7 29:19 33:2 33:7 37:22 50:12 57:8 63:13 64:5 66:6,12 80:23 87:16 89:9 90:15 90:21 95:6
--	--	---	---	---

includes 74:15 77:9 including 11:22 57:4 60:23 69:11 71:19 90:20 96:5 inclusion 54:10 74:10 incorporate 13:21 88:9 independent 33:23 indepth 48:14 index 9:1 individual 13:15,16 77:19 78:22 individually 19:13 57:1 individuals 96:15 industry 28:25 31:4 31:17,22,24 33:5 33:10,18,20 37:3 85:24 86:10 infections 50:21 information 13:10 23:23 25:10,11,13 25:18,22 26:5,6,9 26:12 27:24 28:3 28:6,8,13,15,17 29:20,24 32:11,15 33:16 34:6,11,17 34:22 35:8,23,25 36:21,24 41:6,23 42:4,6,16,19,21 42:25 45:15 46:8 46:24 47:15 48:1 51:2 54:4 61:11 61:16 64:14,18,20 64:23 66:8 71:9 74:11 76:6,9,14 78:1,10,13 81:14 82:8,20,25 86:1 90:15,18,20 95:12 95:13 initial 18:20 87:14 initially 26:1 29:19 35:20 instance 42:11 44:1 45:4 48:3 49:8	79:25 91:11 instruct 13:20 instructions 9:11 86:4 88:24 89:4,9 90:8,12,15,21 instrumentation 94:23 intend 84:5,16,23 85:8,12 intended 70:1,4,4 intending 83:19,21 interest 47:25 63:1 63:3,12,22 64:4 64:16 66:1,2,6,10 interested 98:17 interests 62:12,19 internal 65:3 68:4 68:8 96:5 international 12:9 12:11 29:23,24 30:17 63:13 80:7 internationally 29:1 37:4 69:9,14 71:1,4,18 72:25 74:14 internet 34:5,8 interrelated 88:25 interrelationship 73:15 88:20 interrupt 32:17 inventor 68:23 investigation 80:7 investigations 14:11 77:10 79:19 79:20,22,23 investigator 64:21 investigators 62:13 64:15,16 invoice 60:13 involve 84:9 involved 64:23 involvement 65:12 66:7 isabel 6:3 islands 11:15 isnt 28:20 34:17	iso 63:14,15,18 80:8,9,10,10 issue 41:4 issues 22:3 50:20 itemization 50:6 <hr/> J <hr/> j 34:16,16 jane 5:3 janet 5:23 jeff 53:19 54:3 55:7 59:1 jeffrey 7:12 jennifer 5:9,19 jkuntz 7:15 jo 10:13 joann 4:13 job 97:4 99:3 jog 46:22 johnson 4:1 7:3 36:7,7,8,8 98:1,25 joined 37:6 jones 4:3 joseph 1:5 journal 65:10 judge 1:6 9:5 26:16 26:25 27:15 28:18 64:14 88:5,11 jump 45:3 jumps 44:9 june 11:8 69:7 86:7 jury 83:19,21 84:24 <hr/> K <hr/> kaiser 4:5 kansas 7:14 karen 1:15 2:18 kari 7:17,20 karyn 2:14 kathryn 96:7 keep 67:20 key 56:14,16,18 74:10 kimberly 6:9 kind 45:10,20 61:16 80:19 82:8	86:25 kinds 61:10 kingdom 68:25 kirkpatrick 4:7 knew 17:5 35:20,22 know 18:22 19:1 22:12,16 30:24 32:10,23 33:17,21 36:3,7,9,13,16,24 37:1,7 39:20 40:9 42:5 43:19 44:2 46:23 47:14,23 49:8,25 54:2 55:19 57:5,14 58:10 60:1,6,9 63:20 64:8 65:13 66:8,9,11 68:10 74:7 88:2 91:10 knowledge 37:16 70:2 known 66:20 96:17 96:19 knows 17:7 kristi 7:3 15:23 31:11 98:1,25 kriz 4:9 krystal 6:5 kuntz 7:12 8:5 16:2 21:23,25 23:2 26:19 49:10,18,21 51:24 52:1,5 53:20 54:12 58:16 77:7 78:19 87:2,5 92:15 93:22 94:13 96:2,21 <hr/> L <hr/> label 9:11 22:11 86:4 88:24 89:3,8 labeled 18:5 labeling 8:23 14:6 18:14 25:10,15 81:21 85:18 86:25 87:11,14 89:15 90:6,24 96:12,15 lack 67:5	lady 39:13 large 65:4 late 21:20 22:10 25:2 launch 84:25 laws 97:6 98:21 lee 4:11 lefthand 74:24 lehman 4:13 length 56:17 81:24 level 51:2 56:23,25 57:20 70:9 liability 1:6 licensed 66:2 lifealtering 94:4 lifetime 81:3 limit 60:4 limitations 90:14 limiting 62:5 line 67:7 99:7,9,11 99:13,15,17,19,21 99:23 100:2,4,6,8 100:10,12,14,16 list 23:7,11 32:19 36:10 38:1,25 48:24 53:18,25 54:5 58:21,23 91:11 93:6,8,8,12 listed 19:10 20:9 38:8,14 39:12 49:5,6,24 50:1 54:22 59:17 66:16 69:23 88:1 91:21 92:6,10 93:5,16 93:17 listen 53:19 listening 53:20 listing 16:19 19:9 50:3,11 55:12 lists 53:23 literally 61:13 literature 51:6 57:25 71:20 75:10 75:13 76:4 77:22 93:24 94:1 litigation 1:6 23:6
---	---	--	---	---

Peggy Pence, Ph.D.

Page 108

28:23,24 45:2,6,8 45:10,14,22 46:9 46:22 47:7 little 60:13 live 10:21 llp 7:17 locate 68:12 located 38:15 53:6 long 4:15 11:7,22 15:18 51:9 79:15 80:25 81:6,11 82:14,15,17,25 longer 12:25 13:3 37:25 52:25 longterm 81:6 92:16 look 19:21 27:7,14 36:23 40:13,16,23 41:2,5,8,11 63:17 69:17 71:23 73:3 73:4 76:7,8 80:13 81:16 82:9,11,12 87:10,13 88:21,23 89:1,5,10 90:4 looked 17:5 40:17 40:21,24 41:3 45:7,9 76:5 82:20 looking 30:21 34:10 42:23 44:7 47:22 52:20 54:18 61:22 63:7 76:9 80:1 82:13 85:22 91:21 looks 18:11 19:19 54:19 91:8 loop 35:7 lost 65:4 lot 12:16 34:17 42:20 61:4 louise 3:7 loustauau 4:17 lower 47:4 lozano 4:19	maam 25:1 67:12 70:24 81:23 main 15:13 major 65:2 makeup 32:23,25 making 64:1 81:25 management 14:8 14:9 19:20 manufactured 69:24 manufacturer 31:13 36:20 39:9 70:5 76:7,13 79:3 79:4,12,17 80:2 80:13 81:8,25 83:1 94:10,10 95:10,13,14 96:11 manufacturers 38:18 39:5,12 42:15 49:5 51:4 manufacturing 61:2,5,9 manuscript 65:6,9 65:11 march 1:14 7:4 8:19 10:1 16:20 21:11,17 22:21 24:25 25:3 26:13 31:7 32:7 51:18 51:19 54:1 94:6 97:3 98:23 99:3 marcus 68:23 marcuss 65:8 margaret 4:7 marie 1:10 mark 16:18 17:5,9 18:4 68:24 72:12 marked 14:20,21 16:23 17:6,6,17 18:8,15 20:18,19 21:7,8 27:11 30:25 31:1 37:22 51:14 70:16 71:6 72:1,15,18 86:14 86:16 87:9 market 68:3 77:15	83:2,7,15 marketed 67:5 76:2 76:2 81:9 83:23 88:7 marketing 67:2 71:10 82:2,5,8 83:7,14 marking 16:13 27:10 mary 2:7 3:17 5:3 6:11 mass 45:2 masters 11:13 39:18 material 11:23 12:17 13:7,11 26:6 materials 13:19 23:4,10,15 24:4 mathison 9:5 matter 64:12 maude 31:9,11 38:10,15 40:14 46:20 50:23 51:6 mcbrayer 4:21 mdl 1:5,8 17:6 28:23 58:8 mdr 38:10 39:10 41:5,6,14,16,18 41:20,22 42:2,14 43:1 44:2,3 45:17 47:11,15 48:9 49:3 50:14 76:5 mdrs 40:20 mean 25:7 32:25 47:6,7 meaning 75:5 77:5 measures 90:14 medical 9:8,11 12:12,12,13 13:13 13:18 69:9,24 70:3,14 71:10,17 71:25 73:1,6,23 74:13,18,23 75:4 75:9,13 77:4 81:1 87:14 88:23 89:4	89:7,9,13,15 96:6 medium 75:25 82:13,14,17,24 medtronic 34:2 meeting 34:25 35:17 55:1 94:22 member 34:13,20 34:21 35:22,24 36:8,13 37:12 members 37:5 membership 35:25 36:10,25 37:10 memberships 36:22 memo 89:20 94:16 memorandum 9:5 memory 46:23 82:22 mentioned 28:21 57:18 78:20 80:8 88:25 mesh 15:7 24:15 27:25 28:4 36:20 38:16 45:3 53:9 53:15 57:3,3,7,12 57:21 61:12 92:1 92:3,8,11,12,14 93:3,4,19,21 94:4 94:20 95:4,11,14 meshes 51:7 met 95:10,21 middle 68:17 mind 16:12 52:13 59:1 mine 91:8 minimum 82:12 mint 68:15,20 69:6 minute 32:18 91:18 minutes 85:16 miracle 4:23 miramar 10:15 16:10 miranda 5:7 misrepresenting 30:5 mississippi 7:19	missouri 7:14 misunderstanding 47:1 mix 33:8 mixed 78:24 model 72:25 73:16 modification 78:12 modifications 25:9 moment 63:6 67:10 87:13 moments 94:17 month 32:6 58:14 58:15 morning 10:10,11 multiple 89:17,18 92:19 myra 1:21
<hr/>				
N				
<hr/>				
n 8:1				
name 10:12 14:1 39:13 97:2 99:2,2				
names 39:6,9,9				
nancy 3:23 6:16				
necessarily 18:21				
necessary 86:1				
need 14:16 15:3,18 19:7 52:6,7,11,21 52:25 71:9 73:18 74:20 76:20,24 78:4 79:13,14,15 80:13,23,25 81:3 81:11,25 84:9,12 90:2				
needed 25:21 58:6 84:13				
needs 96:15				
never 21:3 28:12 49:12 68:5				
new 22:3 23:6,9,21 29:7 75:12,14				
newbury 10:20,22 52:22				
newport 7:5 10:1 10:15 16:10				
nice 82:21				

Peggy Pence, Ph.D.

Page 109

nix 5:1	objectives 80:17	67:3,4,9,13,15	91:5 99:7,9,11,13	peggy 1:14 7:2 8:2
noemi 5:5	84:15	74:5,17 75:4,7,15	99:15,17,19,21,23	8:11,12,14,16,19
nonmesh 57:12	obturator 39:8	84:5,6,17 85:17	100:2,4,6,8,10,12	8:21 10:4,13 97:5
nos 78:24	obvious 43:24	85:17,19,21 86:11	100:14,16	97:12 99:2 100:25
notations 45:13	obviously 24:9 33:2	87:1,12 95:4	pages 17:22,22,24	pelvic 1:5 15:7
note 19:19 28:1	42:20 56:23 58:10	opinions 22:3 23:5	17:24	36:20 38:16 51:7
54:23 62:11 64:24	62:2 88:1	23:21,22,24,25	paid 65:23	53:9,15 95:11
noted 65:1 96:23	occur 92:20	25:9,16,19 26:17	pain 50:1,2,18 93:5	penalty 97:1,6 98:5
notes 12:6 98:11	occurred 41:19	27:1,5 28:18 29:5	93:16,17,18,20	98:20
notice 7:6 8:11	42:11 44:22	29:7,12,22,25	pamela 2:22 3:9	pence 1:14 7:2 8:2
14:20 88:15	occurrence 90:10	30:1,4,10,13,14	panel 35:17 94:22	8:11,13,14,16,19
notification 25:14	90:11 92:21,22,22	30:15 61:11,24	paper 66:6	8:21 10:4,13,14
45:11 50:24	ocra 54:25	67:24	paragraph 68:1,13	21:16 27:21 52:17
november 22:13	october 54:21	opportunity 22:9	68:19 71:2 85:22	54:2,17 77:2 96:4
number 8:10 9:4	ocular 81:2	25:6	85:23	97:5,12 99:2
11:11 14:20 16:18	offer 37:8 61:10	orange 17:10,20	park 10:20,22	100:25
16:21 17:3,5,10	84:6,16,23	54:25	52:22	pending 93:13
18:4 20:18 21:7	offered 30:2	order 9:5 27:4,6	parkway 7:18	penny 5:11
27:10,22 40:22	offering 29:7 61:1	28:18 41:15 74:18	part 11:16,23 12:21	people 45:12 64:12
42:14,22 44:19,23	61:6	75:17 76:24 88:5	13:9 27:16 28:18	79:14 80:14,14
46:12 47:19,23	office 10:19,19 11:1	88:12,13	28:24 29:12 38:6	81:10
48:5,6,19 49:7,12	52:23	orders 15:6	53:19 56:8 63:4	percentage 45:3
49:13,16,19 50:19	okay 15:22 54:13	organ 15:7 51:7	67:2,3 71:2	perform 70:4
50:20 57:22 63:18	old 40:8 52:24 53:6	organized 22:1	participated 29:2	performance 9:8
65:4 71:7 72:1,12	53:8	original 20:8 25:11	33:17,18 34:25	14:5 68:5 69:18
72:18 84:8,17,20	older 55:3,5	31:15,20 91:5	particular 13:1	69:21,23 70:14
84:23 85:2,4,21	olson 5:3	originally 56:19	29:1 34:6 38:17	71:25 72:6 73:3,6
86:15,19 87:12	once 65:11	outline 30:20	39:5,11,12 41:13	73:9,11,20 74:1
numbers 17:11,12	ones 14:1,3 15:5	outlined 84:21	43:18 54:23 56:21	84:21 88:22 89:2
17:16 38:23 41:16	18:20,22 19:9,15	outset 68:14,20	57:16 61:4 93:7	performed 68:23
43:21 45:3 47:4	32:9 33:12 34:2	outside 16:17 45:2	particularly 51:7	period 58:11 73:14
47:11 48:4,11	38:4 40:25 46:3	45:6,8	parties 98:18,19	83:9,12
49:3,24 50:4,17	46:21 56:14,16,21	overlooking 54:20	partner 68:24	perjury 97:1,6 98:5
50:18,19,21 51:4	76:11 92:13 94:18		partnership 33:9	98:20
61:18 64:25 84:13	95:16,20		37:3	permanency 92:22
numerous 96:4	oneyear 83:7	padilla 5:5	passage 81:9	permanent 81:4,8
nutshell 66:21	ongoing 32:21	page 8:3,10 9:4	patient 48:3,18	81:14,25 82:3
	online 34:18	18:1 20:3,3 27:16	70:8 90:21	pete 96:6
O	operating 20:6	32:13,20 51:21	patients 65:4 70:6	ph 1:14 7:2 8:2,14
object 21:24 49:10	opine 61:17 83:19	61:18,21 64:24,25	80:23 81:3 83:12	8:16 10:4 97:5,12
87:2 92:15	83:21	64:25 66:16 68:13	patricia 2:8 5:15	99:2 100:25
objection 26:19	opinion 9:5 23:6,9	68:14,17,19 69:8	6:12	phrasing 74:12
77:7 78:19 93:22	23:10 26:20,25	69:19,22,22 70:20	patterson 5:7	physical 70:3
94:13	27:3,15,23 61:2,6	70:25 71:17 73:4	paula 2:16 4:9	picked 57:15,17
objections 21:20	65:14 66:15,18,19	74:13,22 80:10	pays 43:23	pin 71:15
98:6	66:23,24,25 67:2	85:19 89:1 90:6,7	peek 15:1	pipe 21:25

place 98:4	13:17 38:24 41:15	32:15 92:20 93:19	31:15,20,25 52:9	Q
places 19:17 48:13	47:10	93:21	52:17 53:17 58:2	qualifications
plaintiff 7:11	presentation 34:24	proceedings 98:3	59:5,24,25 60:6,7	39:15
plaintiffs 21:21	64:5 65:20 69:6	process 32:12 61:6	60:11,12,18 61:18	qualified 77:19
plan 85:14	presentations	processing 61:9	61:22,25 62:3,10	quality 11:10 14:8
plans 58:1,5	41:13 53:3,4	produce 59:4	63:16 66:20 67:2	14:9 56:24
please 10:12 26:23	54:21,24	produced 55:5	67:5,15,17 68:3,5	question 20:8 24:2
55:10 67:11	presented 29:21	product 39:6 45:7	68:17,21,21,21	26:22 35:12 47:1
plus 40:21	41:21 51:1 65:21	45:20 48:18,19	83:15,20,22 84:18	50:8 62:22,23
point 11:2 49:22	93:17	64:17 66:1,3 79:7	85:6,18,25 91:5	66:22 67:11,25
51:10 56:7,20	presenting 29:4	81:7 83:2 85:25	protection 70:9	68:8 70:23 71:4
61:17 72:24 74:20	pretext 35:15	products 1:5 28:4	protocol 84:10,15	74:17 75:3 76:18
80:21 85:10	pretty 16:3 19:13	38:17 39:7,10,11	84:22 85:1,5	77:13 79:6,11
pointed 92:19	52:19 76:22	40:19 42:12,14	prototype 62:10	81:22 82:10,23
points 79:16 80:17	previous 43:4	45:8,23,25 46:1,6	provide 29:21 54:5	83:10,25 84:16
84:10,14 85:4	46:20 47:16 75:14	46:13 47:13 48:1	59:15 84:12	87:8 88:18 92:24
populate 38:23	86:6	49:4,6 50:7,13,15	provided 21:11	93:13,14 94:5,8
position 23:3	previously 28:21	50:16 51:3 60:5	23:22 59:6 64:21	95:2,9,15 96:3
possibility 94:3	39:24 43:13 76:2	76:7 95:4,19,19	66:8,19 70:6	questioning 62:5
possible 47:12 81:6	primarily 18:11	96:20	81:14 90:20	questions 21:18
posted 38:2	principle 69:23	profession 53:5	provides 83:6,14	36:6 40:10 70:22
poster 64:5 65:20	principles 9:7 14:4	professionals 96:7	ps 22:11	96:21
postmarket 19:6,8	19:21 20:6 69:18	project 13:16 68:11	public 50:24	quick 15:22 16:3
19:23 20:15 67:8	69:20,21 70:13	68:15,20,25 69:6	publication 62:14	20:15 54:12 62:8
67:16	71:25 72:6 73:2,6	prolapse 15:7	64:2,12 66:9,11	96:3
postoperative	73:8,11,19,23,25	24:16 51:8 55:12	publications 15:12	quickly 15:20 16:6
92:16	74:3 80:5,6 88:22	56:10 91:10 92:1	53:6,8 63:2 64:20	18:25 19:13 52:17
potential 64:15	89:2,6,12	93:21	publicly 76:6	56:9
powerpoint 11:24	printed 16:1	prolift 21:12 24:12	publish 64:2 65:1	quite 47:4
12:6	prior 13:17 22:17	24:19,21 25:12	65:11	
practice 62:13	22:22 23:22,24	26:2,7,10,13	published 51:5	R
88:14	24:4 28:22 46:16	28:13,13,15 29:8	57:7 66:5,12	r 1:5
pratt 6:22	69:22 78:12,13	30:2,10 31:1 41:9	75:13	race 94:8
precautions 90:13	82:5,8 88:2,10,15	41:11,21 42:5,8	pull 41:15 42:21	ramirez 51:21 52:6
predate 87:24	88:16 93:14	43:4 44:1 48:4,12	55:17	randomized 55:15
predated 87:15	probability 90:10	50:6 55:22,23	pulled 42:19 46:21	56:22 57:2,6,19
88:9	90:11	58:2 59:25 60:7	55:19	rate 59:18
predominantly	probably 16:1	93:9	purpose 30:17	ratio 69:12 71:22
19:16	18:24 44:5 60:23	proposed 15:6	purposes 70:1	74:19 75:6,18,20
preface 35:15	problem 59:16	proprietary 63:3	77:13	76:15,25 77:6,24
prelaunch 84:18	problems 13:22	63:12 66:2	pursuant 7:6	78:2,5,18 79:9
premarket 67:8,14	50:2	proxima 8:18 15:9	put 14:13 16:12	81:12 82:2,6
76:15	procedure 91:16,22	16:19 17:7,8	17:23 21:19 34:24	rects 55:12 56:10
preparation 60:18	92:7 93:1 94:12	18:19 20:24 21:12	44:19 45:20 50:10	57:11
prescription 85:24	94:21,22 95:1,3	22:24 24:9,19	60:10 71:15 83:15	reactions 91:12,22
present 13:10,11	procedures 20:6	28:1,7,15,17 31:1	96:15	96:17,18

Peggy Pence, Ph.D.

Page 111

read 41:22 42:20 58:7,10,13 88:5 94:17	34:1,3 39:22 43:22 53:12 56:13 60:16 62:7 63:11	regulatory 29:14 29:18 33:3,8,9 54:25 96:7	22:6,24 23:17,21 24:6,8,10,24 25:12,23 26:2,4,7	55:25 58:2,11,14 59:25 60:1 62:14 63:16 92:19
reader 64:13	63:14,23 74:6	reiterate 50:14	26:10,14,18 28:2	represent 72:24
reading 13:11 58:20 59:10 62:16 65:18 75:3 88:16 98:13,14,15	87:19,20 94:2 96:14	related 1:7 13:13 13:18,19 68:4 87:5	28:4,6,7,17,22 30:21,24,25 31:9 31:15,16,20,25 32:2,4,14 38:10	representation 33:20 47:9,10,11 48:11 50:22
reads 75:4	record 23:2 45:13 52:5,14 54:3,12 99:4	relationship 66:1	41:9,11,20,21,22 42:5,8,9 43:18 44:20 45:18 47:15	representative 33:18 51:3 57:23 57:24
ready 60:13	recorded 98:7	relative 74:11 98:17	48:9 50:5,6,11 51:13,17 52:10,18 53:17 54:5,10,11 55:17,19,23 56:15	representatives 33:5,7
real 47:7 54:12 56:9 96:3	records 58:7	released 68:6	58:5,6,20 59:5,8 59:14,17,24 60:6 60:7,8,11,12,18 61:19,25 64:24	represented 33:10 33:11 34:19 43:21 76:12
realize 64:25	reference 15:19 24:12 27:16 38:1 38:16 47:20 63:18 69:2 70:20 71:1 72:5 86:11 88:10 89:1,3	releasing 68:3	65:18 66:12,16 68:12,13 69:17,20 70:20 81:17 85:18 90:4,5 91:6 93:7	request 55:7
realized 28:12	referenced 15:5,11 15:12 17:25 19:16 19:24 20:14 54:9 57:22 68:12 71:11 80:9 86:9,20 88:15 89:8,16	relevancy 88:5	reported 38:15 41:14,20 42:4 44:20,23 47:7,14 47:20,21 50:18,18 50:19,20,21,23	requested 93:9 98:13,15
really 64:7 67:22 78:14 95:9	references 73:5,5 73:12,22,25 80:5 80:7,10 86:3 89:14	relevant 12:10 28:14 29:1 51:6 90:18	reporter 14:22 16:24 17:18 18:9 18:16 20:20 21:9 27:12 51:15 70:17 72:16 86:17 98:2	requesting 25:15
reason 37:8 46:19 57:17 64:17 99:4 99:7,9,11,13,15 99:17,19,21,23 100:2,4,6,8,10,12 100:14,16	referring 19:12 71:5 74:21 75:16	reliance 23:4,11 53:18,23,25 54:5	reports 23:23 24:12 24:16,22 25:11,25 27:24 29:9,11 30:2,11 38:5,10 38:14 39:10 40:13 40:20 41:4,5,6,17 41:18 42:2,14 43:1,4,5,6,9 44:9 44:13,16 45:5,5 45:14 46:7,9,16 47:11,16,19,22 48:11 49:4 50:15 51:1 53:24 54:1	require 65:2 74:18 75:5
reasons 41:4 78:20	refers 82:17	relied 29:12 38:5 54:10		required 62:13 76:16,19
rebecca 6:22	reflect 17:11 29:22	relies 28:25		requirement 68:2,4 68:9
recall 11:11 12:5 12:18 13:24 22:13 22:20,25 26:1 27:6,15 34:14 36:4,15,18 46:16 46:21 47:21 51:10 55:2,23 56:21 57:17 66:13 74:9 82:4 83:16	reflected 90:23	rely 28:11,19 76:10 86:25 88:19		requirements 19:8 20:14
recalling 28:5 41:12 47:18	reflecting 65:3	relying 22:7 30:3,9 67:23 87:11 94:9		research 13:16 33:24
received 25:14	regard 22:10 61:12 81:14 88:18	remained 67:5		reserve 58:5
recess 52:15 54:14 91:19	regarding 8:14,16 29:8 32:15	remarked 65:6		residual 90:8,13,22 95:7
reclassification 15:6 94:23,25	regards 25:10	remember 15:15 46:4		resource 13:19
reclassified 75:25	registry 81:5	remind 11:9 20:12		respect 36:7 49:24 62:18 84:2,5 85:21 96:16
recognized 25:8 68:22 85:24 86:10	regulation 63:5	remotely 10:25 11:1 52:24		responsibilities 20:5
recognizing 29:19	regulations 11:17 28:8,19 29:13 30:3,9,13,15	repair 1:5 15:7 55:13 56:10		rest 88:18 94:6
recollection 12:8 19:2,11 33:25	regulators 33:20 37:2,4,11 82:9	repeat 26:23 31:18 60:3 67:10 70:23 81:22		result 26:3
		repeated 69:16		results 64:3 68:22 83:9
		rephrase 87:4		returned 15:17,20
		report 8:12,14,16 8:19,19,21,21 13:23 15:5,9,13 16:20,20 17:22,23 17:24,25 18:19,21 18:23 19:10,12,25 20:10,23 21:12,16		review 13:9,20 19:7 20:14,15 22:9 25:6 26:16 27:3

Peggy Pence, Ph.D.

Page 112

51:6 59:21 62:7 65:6 74:2 94:19 reviewed 25:5 26:25 27:8,18,19 27:20,21 41:4,5 64:17 95:12,16,17 95:20 96:4 reviewer 64:19 reviewing 27:15 64:13,13 revise 65:8 revisions 25:9 rewrite 65:2 reyes 5:9 rhynhart 5:11 ridgeland 7:19 right 19:10 33:4 35:2 36:11 38:12 40:6 44:16 45:19 58:5 68:7 79:5,6 85:2,12 89:20 92:3,10,24 risk 19:20 25:10 70:6,7 72:7 75:25 75:25 90:9,9,10 90:11,12,13,22,22 95:7 riskbenefit 71:9 risks 89:23 90:2 91:1,2,11,21 92:6 92:10 93:2 94:10 robin 1:17 robinson 65:1,3 96:6 rocio 3:19 roles 20:5 rose 3:5 ruebel 5:13 ruiz 5:15 rule 8:12 77:4 78:6 78:15 79:1,7,8 rules 21:25 23:11 ruling 26:16 run 78:7,17 79:3,13 running 19:14 77:16,17	S s 1:6 29:2,2,18 83:3 83:4 safety 9:7 14:4 45:10 50:25 67:6 67:15,16 68:5 69:18,21,23 70:6 70:10,13 71:25 72:6 73:2,6,8,11 73:19 74:1 84:14 84:21 85:3 88:22 89:2,13 sandra 6:20 satellite 10:19 11:1 52:23 saw 20:9 36:2 55:9 59:13 63:16 saying 18:2 23:7 30:14 46:7 48:12 62:17,25 71:23 77:4 78:7,16 79:2 says 55:15 74:23 75:19 80:13 96:18 school 40:5 scientific 9:6 27:4 28:6 34:1 36:11 36:13 43:7 48:19 56:6 75:9 95:18 scope 26:17 27:1,4 69:1 scrape 16:17 search 38:19,22 39:1,4 41:17 searches 34:10,12 46:20 searching 34:5 second 67:4 72:19 89:6 section 32:13,13 37:20 68:17 88:24 92:7 secure 39:8 see 18:2 20:3 27:18 34:11 37:19,24 41:12 44:9,10 58:21 59:7,17	73:4,9,21 85:19 88:13 89:3,7,14 90:7 91:13 94:4 seeing 34:14 45:4 seen 45:3,5,9 59:12 66:13 82:4 93:24 94:1 selected 54:21,21 sell 78:8 sends 66:9 sense 29:16 sentence 68:19 69:5 71:16,23 74:22 75:1,3 separate 17:20 47:17 67:19 separately 21:4 separating 94:20 95:3 seriously 80:13 session 54:24 set 29:8 30:10 36:24 43:4 51:20 61:25 77:3 79:14 80:1,12,16 84:14 86:10 95:21 96:10 96:11 98:4 sets 70:19 79:17,18 81:11,24 82:3,5 86:24 87:8,10 89:22 setting 90:1 severity 90:12 92:21 94:3 sharon 1:13,23 sheet 99:1 100:1 sherry 2:20 shes 23:5,7 40:11 shipped 16:9 shirley 2:24 short 82:12 shorthand 98:2,11 show 67:15,16 69:11 76:25 83:17 showing 35:8 67:6 shows 41:23 83:17	shultis 5:17 side 17:11 74:24 90:20 95:6 signing 98:13,14,15 sikes 5:19 similar 27:19,23 76:4,8,17 90:1 similarity 76:2 sit 12:19 19:2 22:25 26:1 33:13 34:3 34:15,22 36:1,4,9 36:15,18 39:22 41:12 43:19,22 46:5,16 47:18 56:20 57:14 58:1 58:3,4 60:16,24 61:9 63:14 66:13 82:4 85:8,14 sitting 63:23 sixth 12:1 13:1 size 80:2,12 slack 62:10 68:24 slides 11:24 12:6 sling 39:7 40:18 42:12 44:8 48:4 slings 49:8 slow 72:9 smith 5:21,23 snow 7:17 sold 49:9 sole 88:19 somewhat 31:25 son 40:12 sop 88:15 sorry 12:21 19:23 31:18 60:3 91:9 sort 37:17 49:7 81:10 sounded 76:22 southern 1:2 speaking 14:7 specific 12:1 13:8 13:25 33:15,19 34:22 36:21 37:8 40:22 41:17 42:3 50:7 51:3 58:4	61:8,16 77:11 83:21 84:8 85:4 93:12 specifically 12:19 14:2 19:18 22:25 27:7 33:13,17 34:10,14 36:4 40:9 46:4 47:22 49:2 58:10 77:18 82:5 spent 60:14 splice 48:5 springer 6:1 squared 52:3 stacy 5:17 staff 17:7 38:21 41:7,15 52:24 standard 29:24 57:24 62:12,17,24 63:7,10,21 69:9 69:15 70:19 71:1 71:5,18,24 72:4 72:19 73:24,25 74:14 75:8,16,19 76:3 79:12,16,20 80:1 81:10,16,24 82:2,5 85:24 86:10,25 87:9,11 87:15 89:23 90:1 90:7 94:9 95:11 95:21 standards 28:11,25 29:3,4,17,19,23 30:18 31:4,17,22 31:25 63:13,15,19 64:9 67:23 70:21 71:11,12 73:17 74:10 77:3 80:8,8 80:8,9,16 88:2 95:2,7 stands 31:12 stapled 21:4 start 11:5 69:21 73:2 96:19 starting 32:13 starts 11:6 74:24
--	--	---	--	--

Peggy Pence, Ph.D.

Page 113

91:15 state 11:13 51:1 97:6 stated 23:20 56:14 75:8 77:8 90:4 94:18 statement 37:17 74:21 states 1:1 29:15 stating 94:19 statistician 80:22 84:9,12 statistics 80:4,15 85:2 sted 89:13 stenographically 98:8 stick 16:16 44:3,8 sticker 16:16 stickers 16:12 stip 62:7 stored 42:16 street 16:8 strength 56:17 students 11:12 studies 19:6,24 57:16 67:1,1,6,14 67:16,21 71:20 74:16 75:11 76:15 76:19,24 78:4 study 32:19,20,24 33:22 34:13 35:11 36:16,22 57:1 62:14 65:2 79:23 80:25 81:5 84:7 subject 100:19 submitted 39:11 49:4 50:15 60:13 65:5 submitting 62:14 substantiate 76:13 77:23 78:1 substantiates 29:25 substantiation 25:16 suite 7:5,13,18	sum 43:3 summarized 55:24 summary 89:11 superseded 88:16 supersedes 86:6 superseding 86:23 supervision 98:9 supplement 16:25 17:1 24:20 28:12 32:7 42:9 58:2,5,6 supplemental 8:14 8:16,19,21 16:20 19:25 21:12 22:6 23:10,11,17,20,22 24:5,8,21,23 25:23 26:13,18 30:21,24,25 32:1 32:4,14 38:10 50:11 51:13,17 53:24 54:1,5,10 59:24,25 60:7,8 60:18 69:17,20 81:17 90:5 supplementary 32:15 supplements 16:22 supplied 26:13 support 13:11 23:4 23:10 29:5,12 30:3,9,13 34:11 67:1 73:16,17 supported 30:14,16 supporting 8:20 supportive 23:24 25:8,19 supports 69:4 supposed 53:25 sure 13:5 15:18,22 15:24 16:17 19:2 21:1,15 32:11 33:1 50:9 52:3 53:18,24 54:7 55:7 65:13 surgeries 92:3,6 surgery 91:1 surprises 64:8	surveillance 19:8 20:15 susan 3:11 6:7 suspect 12:7,13 sutherland 7:17,20 8:4 10:9 14:19,23 16:7,16 17:2,9,14 17:19 18:10,13,17 20:17,21 21:6,10 21:18,24 22:5 23:13 26:21 27:9 27:13 49:15,23 51:12,16,20,25 52:2,7,8,14,16 53:22 54:13,15,16 58:17 70:18 72:12 72:17 77:12 78:23 86:13,18 87:3,7 91:18,20 92:23 93:23 94:15 95:23 96:22 swanson 38:21 39:14 51:9 swint 6:3 sworn 10:5 syllabus 14:12 symbion 42:17 system 1:5 systems 8:18 14:8 14:10 16:19 <hr/> T <hr/> tab 79:21 89:6,10 table 41:16 88:23 tabs 16:21,22,22 17:10,15,20 tabular 41:13 tabulate 42:21 tabulation 41:16,20 42:2,3,13 43:2 48:25 49:2 50:17 tailored 22:2 take 8:11 15:1,25 27:7,14 taken 7:2 15:17,19 43:20 64:18 90:15	98:3,11 takes 42:19 talk 22:2 54:2 64:8 81:20 talked 46:20 62:2 63:10 67:21 77:3 78:16 79:2 89:19 talking 12:15 24:16 35:4 43:3 61:11 61:13 63:20,25 64:1,6 65:15,22 68:9 74:23 75:21 75:23 76:1,12 77:14,14,17 82:16 91:10 93:12 94:21 talks 14:8 71:17 82:24 tally 49:3 50:14 tape 8:17 16:13 task 9:7,9,10 11:20 70:13 79:24 taught 12:9,24 13:3 teach 11:9,14,16 12:1,2,12,23 13:1 14:14 teaching 11:3,5,17 11:19 team 65:9 teams 65:3 teasley 6:5 technical 70:2 89:11 teenager 40:11,12 tell 10:12 11:25 14:2 18:24 21:4 27:8,14 31:11 32:9 33:13,16 37:25 38:11,11 39:1,3,20 40:18 40:20 43:11 56:9 56:17 57:15 59:19 60:11 62:24 64:7 67:6 72:10 79:13 92:6 telling 54:17 88:4,8 89:17	tells 94:10 ten 82:25 tension 8:16 teresa 3:3 term 47:12 82:12 82:14,14,14,15,17 82:18,25 terms 38:22 41:17 77:22 test 25:19 testified 10:6 29:7 48:5 76:20 testimony 22:10 27:22 30:1,8 35:19 58:21,23 59:21 96:10,18 98:6,12 thaman 6:7 thank 27:17 thats 14:20 15:20 16:25 17:8 18:5 26:8 27:8,14 30:5 32:22 37:13 40:12 42:13 43:3,24 46:22 47:15 48:10 49:10 55:4 56:23 59:16 60:13,24 64:11,17 66:15 69:23 70:15 75:1 75:8,12,19 76:6 80:4,15 81:2 83:1 83:8 85:14 86:9 87:19 88:1 93:10 93:16 95:22,23 96:9 theres 12:16 22:3 31:9 37:5 40:19 41:18,23,24 43:16 45:10 50:6 73:15 76:14,25 78:15 90:6 93:13 96:17 theyre 21:4 35:24 41:7 47:7 56:16 thing 32:10 62:9 85:20 things 23:7 53:1
---	---	--	---	--

66:20 67:20 think 12:24 13:3 16:2,5 21:3,4,25 22:1,3 23:3,9,9 26:10 38:11 46:19 48:5,6 51:21 55:2 55:4 60:20 62:20 68:16 74:20 76:18 77:1 78:24 79:13 82:10,23 83:10 84:18 87:22 92:25 94:6 thinking 12:20 13:21 63:9 third 89:10 thirteen 22:14 thomas 6:9 thought 23:23 25:16,24 26:2 56:4 57:23 three 16:21 23:8 38:14 82:14,17 thurston 6:11 time 11:2 15:16,20 26:19 27:2 32:6 32:21 33:15 34:20 35:6,9,16 42:20 56:20 57:25 60:17 61:17 75:22 78:25 81:24 83:9,12,18 85:10 88:8 96:23 98:4,5,7 times 33:15 49:12 title 79:22 titled 8:18 32:14 today 12:19 14:24 19:3 23:1 26:2 33:14 34:3,15,23 36:1,5,9,15,18 39:22 41:12 43:19 43:23 46:5,16 47:19 51:8 56:20 57:14 58:1,3,4 60:16,25 61:9 63:14,24 64:8,10 66:13 82:4 85:8	85:15 told 39:3,4 87:23 90:3 93:3 top 44:7 55:15 68:14,18 90:7 total 40:19 42:14 49:3 totaled 60:17,22 totaling 60:24 totality 76:9 totals 45:24 track 30:19 tract 50:2,20 training 70:3 transcribed 98:8 transcript 22:16 23:15 98:11 100:20,22 transcription 99:5 transfer 37:9 transferred 37:1 transvaginal 15:7 51:7 treat 24:16 treatment 81:2 treatments 82:7 tremendous 12:17 trial 23:12 27:1 58:24 75:17 77:16 77:18 78:7,17 79:14 80:2,16,18 81:11 83:22 84:18 84:24 85:4 trials 11:10 55:16 56:23 57:2,6,20 77:5 78:3 79:3 tried 72:13 trolling 34:8 true 97:7 98:10,21 100:20,22 try 43:10,11,23 66:17 67:19 78:25 trying 30:5 34:5 40:2 46:22 60:4 67:7 72:24 87:22 turn 66:15 85:17	91:5 turnaround 15:22 turned 16:3 turning 81:17 tv 30:25 39:7,7,8,8 39:8 43:6 44:1 46:7,11 48:9,10 48:11 49:8 50:5 51:13,17 59:25 60:8,18,23 87:21 94:7 tv 39:7 51:18 twelve 22:14 two 12:20,22,25 13:4 15:16 24:21 30:22 31:2 48:6 67:19 twothirds 68:1 twoyear 83:8 tyler 6:12 type 41:16 42:5 45:11 51:2 95:13 typed 59:11 types 29:24 48:15 49:25 50:7 typical 88:14 typically 13:24 45:9 93:19	75:15 understood 35:19 undertaken 73:18 unfortunately 42:7 united 1:1 29:15 68:25 university 11:14 unload 86:13 upcoming 14:13 update 12:6 50:24 52:21,25 55:8 73:7 updated 46:17 53:25 54:19 55:4 55:8,25 59:3 88:1 updates 25:15 73:13 updating 26:4 urinary 50:2,20 urology 8:15 use 9:11 13:7 14:1 14:3 38:22 47:12 70:7 75:5 86:4 88:24 89:4,9 90:8 90:12,16,21 91:2 92:8,11,14 93:2 93:21 user 31:13 users 70:4 usually 14:7 utilize 13:25	vague 26:19 87:2 92:15 variety 41:3 69:16 various 13:11,12 33:11 73:17 83:16 94:20 verified 38:7 verify 41:7 version 54:19 74:8 74:8 86:6 versus 94:11 virginia 1:2 virtue 64:15 70:1 vitro 74:11 voluntary 37:10 vs 9:5 97:2 99:2
W				
wagstaff 7:12 waiting 14:17 waive 21:20 waived 98:14 want 15:14 16:2,9 16:15 43:15 53:19 55:8 62:9 64:7,9 65:13 67:25 70:21 70:21 72:9 77:15 81:5 82:11,21 85:20 87:13,14 wanted 29:21 53:18 53:24 54:7 88:1 warehouse 61:14 warlick 6:14 warn 89:23 90:2 94:11 warnings 90:13,23 96:20 wasnt 59:6,12 wave 1:7 58:8 way 17:23 26:24 30:12 57:6 58:13 62:19 68:1 69:25 94:4 ways 15:16 91:25 wcllp 7:15 website 37:18,23				

Peggy Pence, Ph.D.

Page 115

37:24 38:3,6 wednesday 7:4 10:1 week 58:16,18 weeks 12:17 14:18 51:22 60:17 weighed 70:8 weisberg 23:18 96:6 weisbergs 22:10 23:14 24:2 25:6 went 38:7 61:4,5,14 west 1:2 weve 84:14 whats 38:8 53:1 75:8 82:12 89:5 white 8:23 16:18 18:14 williams 6:16 wilma 4:1 wiltgen 6:18 wishes 65:8 witness 8:2 10:5 16:4,25 17:13 49:20 53:21 77:8 78:20 92:17 94:14 98:5,6 99:2 wolfe 6:20 women 84:6,8,17 womens 8:15 wondering 81:23 wont 49:18 61:10 words 13:25 work 10:25 15:21 37:9 45:20 60:2,5 60:10 65:8 worked 36:3 39:24 51:9 working 11:1,12 14:16 29:14,18 34:23 35:6,9,10 35:16,21 52:24 83:13 works 82:9 83:1 worktable 61:15 worlds 65:7	worries 31:19 56:3 wouldnt 29:16 47:5 52:13 wrap 94:5,8 write 17:8 84:9 written 59:7 62:24 69:15 71:16 79:16 wrong 61:5,14 wrote 28:1,5,7 86:6 X x 8:1 98:15 Y year 12:1,2,4,7 13:1 44:12,15,18 44:19 51:10 55:1 82:12 years 12:14,20,22 12:25 13:4 23:5,8 28:23 35:24 36:2 36:3 49:7,21 50:16 58:12,22 73:14 82:15,17,18 82:24,25 yellow 17:10 yeses 78:24 youd 48:6 youll 26:23 28:1 61:21 73:4,9,21 88:14 89:2 youre 14:13 18:2 22:7 29:7 30:3 43:3 45:4 60:22 61:1,8,11 62:11 62:25 63:20,25 65:14 67:23 71:5 71:23 74:21 75:16 77:17 80:15,17,19 81:2,4,16 82:16 86:24 87:11 89:17 94:9 Z 0 000 40:21 44:12,16	45:5,5,21 60:14 083 40:19 1 1 1:7 8:11,18 14:20 14:21 19:17,18,24 20:2,4 22:8,17 23:16 24:5 31:24 32:1,14 54:21 58:8 69:17,19 81:19,21 90:5 99:4 10 8:4 9:7 70:15,16 71:7 72:1 73:7 88:21 89:1 100 7:5 60:23 1020 7:18 11 9:9 20:3 32:13 32:20 72:12,15,18 73:4,22 96:23 1124 7:14 12 7:5 9:10 10:2 12:17 86:15,16,19 125666 97:4 99:3 12585 7:4 98:1,25 12cv00258 5:22 12cv00261 2:7 12cv00279 6:8 12cv00344 3:6 12cv00347 4:20 12cv00358 2:11 12cv00368 1:14 12cv00369 3:14 12cv00423 2:23 12cv00443 4:4 12cv00455 3:10 12cv00469 6:13 12cv00470 5:4 12cv00476 1:12 12cv00481 5:8 12cv00483 2:2 12cv00486 2:19 12cv00493 3:24 12cv00499 6:10 12cv00500 6:6 12cv00501 5:20	12cv00505 6:11 12cv00510 4:24 12cv00511 6:17 12cv00516 2:9 12cv00517 4:14 12cv00554 1:24 12cv00567 5:6 12cv00595 3:18 12cv00651 1:18 12cv00654 5:18 12cv00663 5:14 12cv00666 4:18 12cv00683 3:8 12cv00746 4:8 12cv00747 2:15 12cv00748 1:22 12cv00779 4:22 12cv00786 6:4 12cv00806 3:22 12cv00809 4:2 12cv00829 3:4 12cv00848 2:17 12cv00861 5:24 12cv00878 2:21 12cv00887 4:6 12cv00931 2:6 12cv00938 4:10 12cv00957 3:2 12cv00960 1:9 12cv00997 6:2 12cv01011 3:16 12cv01013 4:12 12cv01021 5:16 12cv01023 1:20 12cv01119 5:12 12cv01121 3:12 12cv01215 1:16 12cv01216 6:19 12cv01267 2:4 12cv01273 6:23 12cv01275 4:16 12cv01278 5:2 12cv01294 3:20 12cv01299 2:13 12cv01318 1:11 12cv0276 6:15	12cv0335 6:21 12cv05664 5:10 12th 79:24 13 60:15,15 88:24 14 8:11 60:15 1400 7:18 141551 80:10 141552 80:11 146 86:3,9,20 14th 98:23 15 85:16 150 80:14 1533 10:15 16:10 16 8:18 44:16 45:5 45:21 17 8:20 18 8:22,23 61:21 62:9 68:13,16 1991 89:20 1999 39:4 1st 20:24 28:2 59:5 60:12 2 2 1:9,11,12,14,16 1:18,20,22,24 2:2 2:4,6,7,9,11,13,15 2:17,19,21,23 3:2 3:4,6,8,10,12,14 3:16,18,20,22,24 4:2,4,6,8,10,12,14 4:16,18,20,22,24 5:2,4,6,8,10,12,14 5:16,18,20,22,24 6:2,4,6,8,10,11,13 6:15,17,19,21,23 8:12 20:18,19 38:9 42:9,24 43:12,21 51:19 52:17 54:18 56:1 66:23,24 67:2,3,4 67:13 69:22 99:4 20 8:12 64:24,25 73:14 97:9 200 1:8 2000 87:16,25
--	---	---	---	--

Peggy Pence, Ph.D.

Page 116

2003 44:22 80:11	3	67 60:14		
2005 69:7 73:8,12	3 8:14 21:7,8 44:12	7		
74:2,8 86:7,23	45:5 53:17 69:19	7 8:22 18:4,8 88:24		
87:15 88:3 89:15	85:19,21 86:11	70 9:7		
2006 37:6	87:12 99:5	701 7:14		
2007 44:23,23 72:8	30 23:12 49:11	72 9:9		
72:10,11 73:10	300 7:13			
2008 50:24 56:15	32 66:16	8		
57:25	33 69:8 70:20,25	8 8:23 18:13,15		
2009 83:17	71:17 74:13,22	20:3 37:22 79:21		
2010 49:9 79:24	34 60:14	89:5,11		
83:17	35 91:5	816 7:14		
2011 34:24 35:8,10	36 91:5	86 9:10		
35:16,17 44:9	391586010 7:19			
50:25 51:5 86:23	3rd 21:17 24:25	9		
87:15 88:3	31:7	9 1:14 7:4,5 9:5		
2012 25:12 26:7	4	10:1,2 27:10,11		
29:9,11 30:2,10	4 8:16 32:13 51:14	27:16,22 28:20		
37:15 44:12 45:4	85:19	97:3 99:3		
56:15 57:25 73:7	40 69:2,4	92661 10:16 16:11		
74:8	41 20:2 85:19	96 8:5		
2013 44:15 45:5	42 85:19	985 7:19		
54:21,22	45 96:23	99 46:7		
2014 26:10 28:5	4523 7:19			
29:9,11 30:2,10	4740 7:13			
55:2 56:20 57:19	5			
2015 22:10,15 27:3	5 8:18 16:18,23			
28:21 39:5 46:7	17:3 55:12,20			
46:14,15,17,18	57:8 79:23 80:10			
55:2	90:6			
2016 1:14 7:4 8:18	50 80:13			
8:19 10:1 20:24	500 59:20			
21:17 22:8,17,24	51 8:16			
23:16 24:5,10,25	516 11:11			
26:13 28:17 31:7	54 63:4			
31:16,21 46:18	5600 7:5			
51:18,19 60:12	5th 11:6			
97:3 98:23 99:3	6			
20year 32:21 37:2	6 8:20 17:5,10,17			
21 8:14 63:4	73:4 90:7			
23 40:19,21	60 60:23			
2327 1:5	601 7:19			
24th 94:6	64112 7:14			
26 8:12				
27 9:5				
270 44:9				